



EXHIBIT 34

U.S. Patent No. 8,273,308 Infringement Chart

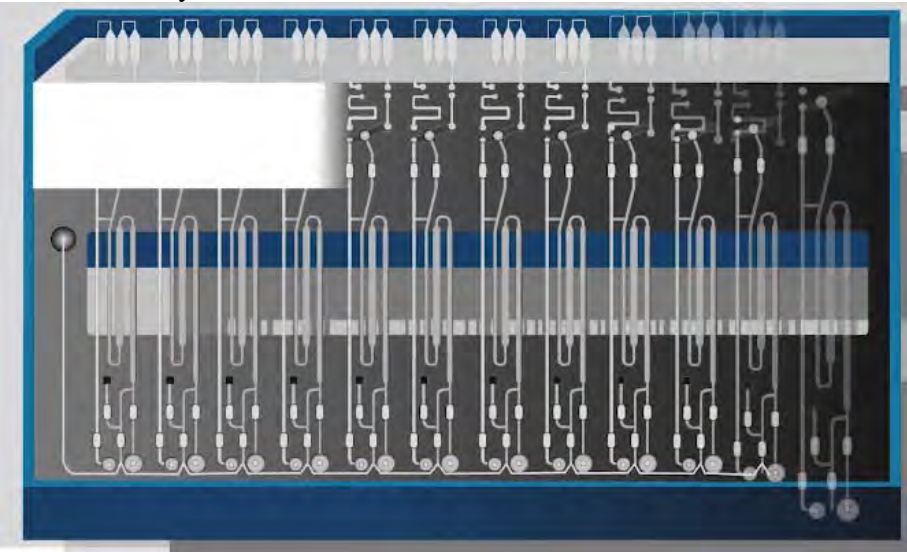
Claim	Claim Language	Infringement Evidence
1(a)	A system, comprising:	<p>To the extent the preamble is limiting, the accused instruments are a system.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p>  <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited</p>

Claim	Claim Language	Infringement Evidence
		<p>May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of

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		<p>the instrument with touchscreen computer, accessories, and reagents and consumables.”</p> <ul style="list-style-type: none"> • “NeuMoDx™ Molecular Systems are versatile; in addition to IVD tests, our system can also be used as an open system to process Laboratory Developed Tests (LDTs) that have been created and validated by your lab.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, last visited May 31, 2019, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> • “There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”
1(b)	a microfluidic device	<p>The accused system comprises a microfluidic device.</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

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		 <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 24, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from ‘sample to result’. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-

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		<p>sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.”</p> <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>0600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • “NeuMoDx™ RELEASE Solution INSTRUCTIONS FOR USE... The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) and the dried Master Mix contained in a NeuMoDx test strip. The System then dispenses the prepared RT-PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.” <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> • “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.”

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		<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <p>“Patents”, http://www.neumodx.com/patents/, demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 9,539,576; 9,637,775; and 10,093,963. (Exhibit 15)</p>

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		<div><h2>PATENTS</h2><table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.</td></tr></table></div> <div><p>US10041062 (Exhibit 33)</p><ul style="list-style-type: none">Claim 1. A molecular diagnostic system configured to process a biological sample within a cartridge and separate a nucleic acid volume from the biological sample, the molecular diagnostic system comprising: a cartridge platform that supports the cartridge and comprising a magnet receiving slot configured to be aligned with the cartridge in a first operation mode; a nozzle of a liquid handling subsystem; an optical subsystem; a cartridge heater; a magnet vertically aligned with the magnet receiving slot; and an actuator coupled to the nozzle of the liquid handling subsystem, the optical subsystem, and the cartridge heater, the actuator configured to vertically displace the cartridge platform in the first operation mode to a position wherein: the nozzle of the liquid handling system is coupled to a fluid port of the cartridge, wherein the fluid port of the cartridge receives fluids for processing the biological sample, the magnet passes through the magnet receiving slot of the cartridge platform and interfaces with a first portion of the cartridge, the optical subsystem interfaces with a second portion of the cartridge, wherein the second portion of the cartridge receives a processed derivative of the nucleic acid volume, and a third region of the cartridge is compressed between the cartridge heater and the cartridge platform.</div>	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636.	XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.
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		<p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater.
1(c)	a computer-controlled heat source; and	<p>The accused system comprises a computer-controlled heat source.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary

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		<p>NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection

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		<p>chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating

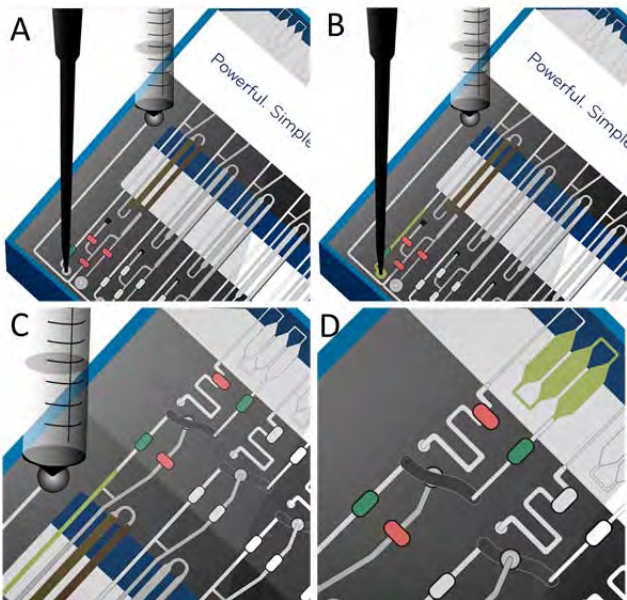
Claim	Claim Language	Infringement Evidence
		<p>layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 2:21-32 (“As shown in FIGS. 1A and 1B, an embodiment of a system 100 for thermocycling biological samples within detection chambers comprises: a set of heater-sensor dies 110; an electronics substrate 140 that couple the set of heater-sensor dies to a controller; a set of heat sink supports 150 coupled to at least one of the electronics substrate and the set of heater-sensor dies; and a set of elastic elements 160 coupled to the electronics substrate and configured to bias each of the set of heater-sensor dies against a detection 30 chamber. In some embodiments, the system 100 further comprises a controller 165 and/or a cooling subsystem 170 configured to actively cool the system 100.”) U.S. Patent No. 9,499,896 at 9:11-19 (“As shown in FIGS. 1, 4A-4B, and 7A-7C, the system 100 can further comprise an electronics substrate 140 configured to couple heating and sensing elements of the set of heater-sensor dies to a controller 165, a set of heat-sink supports 150 configured to facilitate heat dissipation within the system 100, a set of elastic elements 160

Claim	Claim Language	Infringement Evidence
		<p>configured to bias the set of heater-sensor dies 110 against detection chambers for sample processing, and can additionally comprise the controller 165 and/or a cooling subsystem 170.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 12:20-31 (“In a specific example, the controller 165 comprises a Yokogawa UT750 PID controller, an Arduino UNO R3 microcontroller configured to cycle the UT750 through temperature stages and to control temperature holding, a resistance-to-voltage conversion circuit, and two power supplies—a first power supply configured to supply power to the set of heater-sensor dies 110 and a second power supply configured to supply voltage to the resistance-to-voltage conversion circuit. In the specific example, the controller 165 comprises a resistance-to-voltage conversion circuit because the UT750 PID controller requires voltage as an input for PID control.”) U.S. Patent No. 9,499,896 at 11:63-12:4 “As shown in FIGS. 1A and 1B, the system 100 can further comprise a controller 165, which functions to automate and/or control heating parameters provided by the set of heater-sensor dies 110. The controller 165 can further be configured to provide heat parameter output commands to the heating element(s) 114, and/or configured to receive communication of heating parameters (e.g., detected temperatures) sensed at the sensing element(s) 115 of the system 100.”
1(d)	a detector;	<p>The accused system comprises a detector.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/product/neumodx-288/, last visited June 3, 2019 (Exhibit 13)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/product/neumodx-96/, last visited June 3, 2019</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of

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		<p>products of amplification.”</p> <p>JFO_2018-10-25_8009-Rev-B_NeuMoDx-96-Spec-Sheet (Exhibit 21)</p> <table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>NeuMoDx 288 Spec Sheet R2.pdf (Exhibit 22)</p> <table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>US10041062 (Exhibit 33)</p> <ul style="list-style-type: none"> Claim 1. A molecular diagnostic system configured to process a biological sample within a cartridge and separate a nucleic acid volume from the biological sample, the molecular diagnostic system comprising: a cartridge platform that supports the cartridge and comprising a magnet receiving slot configured to be aligned with the cartridge in a first operation mode; a nozzle of a liquid handling subsystem; an optical subsystem; a cartridge heater; a magnet vertically aligned with the magnet receiving slot; and an actuator coupled to the nozzle of the liquid handling subsystem, the optical subsystem, and the cartridge heater, the actuator configured to vertically displace the cartridge platform in the first operation mode to a position wherein: the nozzle of the liquid handling system is 	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass
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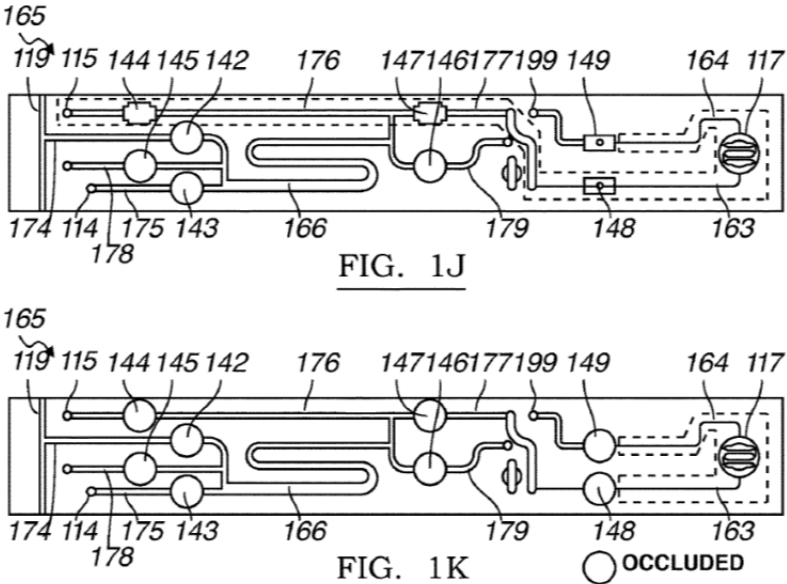
Claim	Claim Language	Infringement Evidence
		<p>coupled to a fluid port of the cartridge, wherein the fluid port of the cartridge receives fluids for processing the biological sample, the magnet passes through the magnet receiving slot of the cartridge platform and interfaces with a first portion of the cartridge, the optical subsystem interfaces with a second portion of the cartridge, wherein the second portion of the cartridge receives a processed derivative of the nucleic acid volume, and a third region of the cartridge is compressed between the cartridge heater and the cartridge platform.</p> <ul style="list-style-type: none"> Claim 8. The system of claim 1, wherein the optical subsystem comprises at least one unit including an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the biological sample, and to transmit emitted light from the biological sample, through the emission filter, and toward the photodetector. <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater.

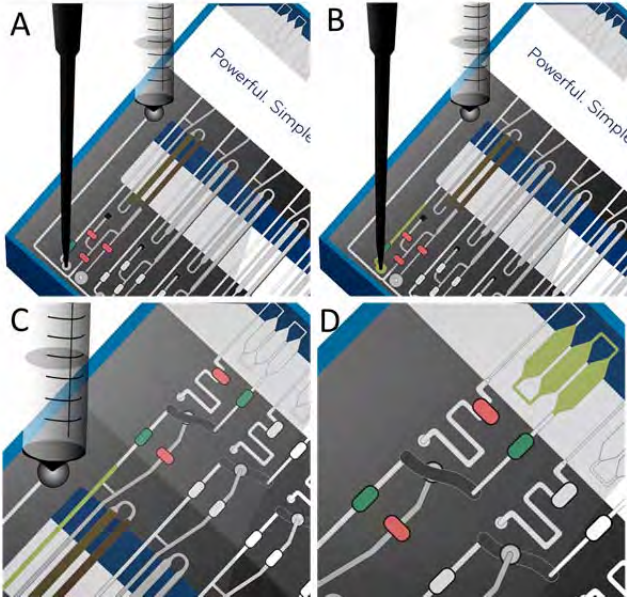
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 11. The system of claim 1, wherein the molecular diagnostic module further comprises an optical subsystem comprising a first unit and a second unit, wherein each of the first unit and the second unit includes a set of excitation filters, a set of emission filters, a set of photodetectors aligned with the set of emission filters, and a set of dichroic mirrors configured to reflect light from the set of excitation filters toward one of a set of nucleic acid-reagent mixtures at the cartridge, and to transmit emitted light from one of the set of nucleic acid-reagent mixtures, through at least one of the set of emission filters, and toward at least one of the set of photodetectors. Claim 12. The system of claim 11, wherein the molecular diagnostic module further includes a set of detection chamber heaters configured to heat a set of detection chambers through the second surface of the cartridge, and wherein the optical subsystem is configured to receive light, emitted from the set of nucleic acid-reagent mixtures at the set of detection chambers, from the first surface of the cartridge.
1(e)	wherein the microfluidic device comprises: an upstream channel;	<p>The accused system comprises a microfluidic device comprising an upstream channel.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

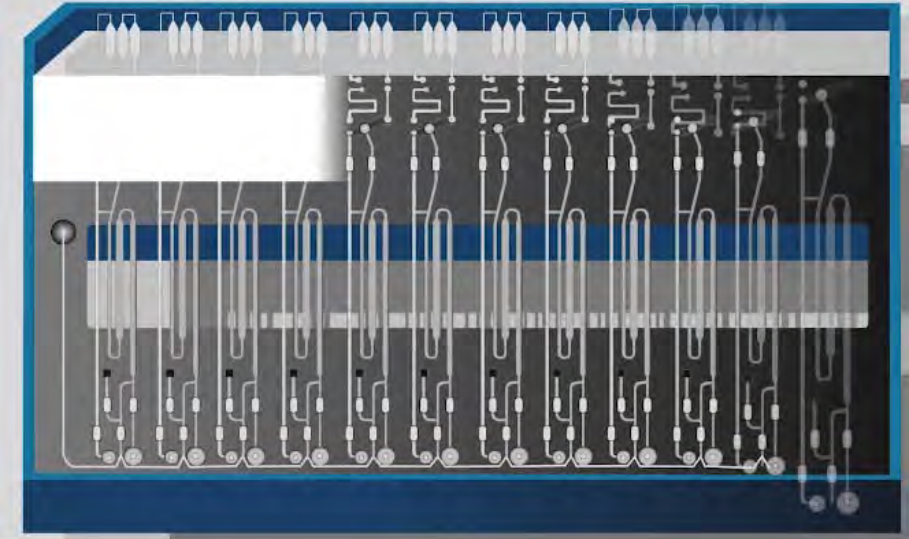
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 911 1115 943">US9738887 (Exhibit 31)</p> <ul data-bbox="842 951 1913 1390" style="list-style-type: none"> • Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent port, the fluid port, and the detection chamber.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of Detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region”) U.S. Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) U.S. Patent No. 9,738,887 at 15:31-35 (“The segment running to a detection chamber 163 functions to deliver a processed sample fluid to the detection chamber 117 with a reduced quantity of gas bubbles, and the segment running away from the detection chamber 164 functions to deliver a fluid away from the detection chamber 117.”) U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the

Claim	Claim Language	Infringement Evidence
		<p>sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at Figs. 1J and 1K:


Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 23:36-41 (“Each detection chamber 117 of the specific embodiment is identical and comprised of three interconnected channels, configured in a circular arrangement, with each of the interconnected channels approximately 0.4 mm deep and 1.6 mm wide at its widest point, resulting in a total volume of -10 mL for each detection chamber 117.”)
1(f)	[the microfluidic device comprises] a DNA manipulation module located downstream from the upstream channel;	<p>The accused system comprises a microfluidic device comprising a DNA manipulation module located downstream from the upstream channel.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the

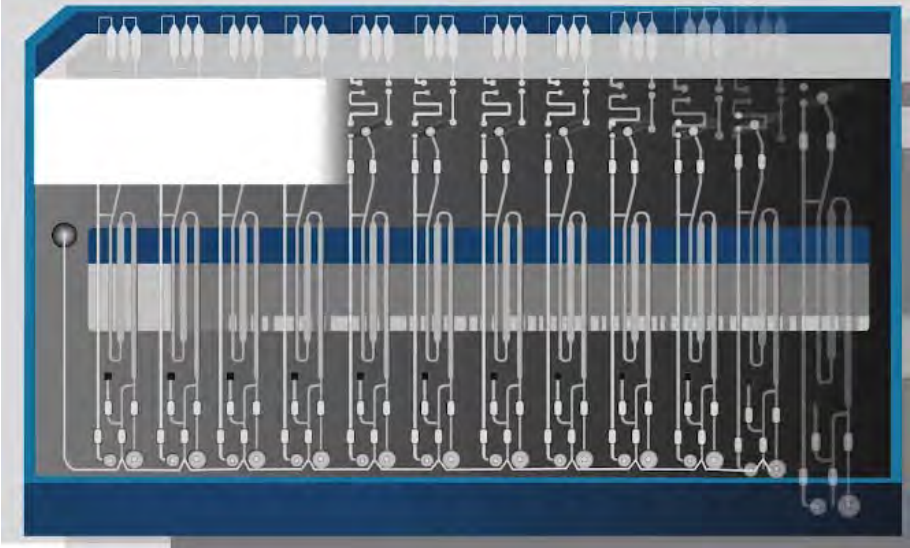
Claim	Claim Language	Infringement Evidence
		<p data-bbox="890 235 1816 302">cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08</p>  <p data-bbox="793 980 1877 1052"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="846 1062 1913 1240" style="list-style-type: none"> • “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.”

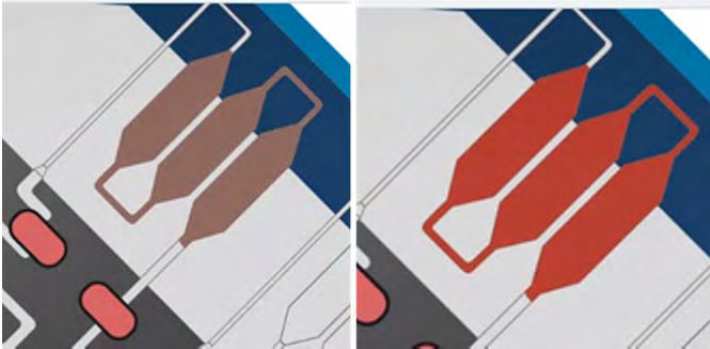
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 • U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of Detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 2:36-3:5. (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140.. In a specific application, the microfluidic cartridge 100 can be used to facilitate a PCR procedure for analysis of a sample containing nucleic acids.”) U.S. Patent No. 9,738,887 at 13:7-18. (“The top layer 110 of an embodiment of the microfluidic cartridge 100 functions to accommodate elements involved in performing a molecular diagnostic procedure (e.g. PCR), such that a sample containing nucleic acids, passing through the cartridge, can be manipulated by the elements involved in performing the molecular diagnostic procedure. The top layer 110 is preferably composed of a structurally rigid/stiff material with low autofluorescence, such that the top layer 110 does not interfere with sample detection by fluorescence or chemiluminescence techniques, and an appropriate glass transition temperature and chemical compatibility for PCR or other amplification techniques.”) U.S. Patent No. 9,738,887 at 13:35-42. (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) U.S. Patent No. 9,738,887 at 15:29-39 (“The segments may be arranged in at least one of several configurations to facilitate isolation, processing, and

Claim	Claim Language	Infringement Evidence
		<p>amplification of a nucleic acid sample ...”).</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 23:20-24 (“The top layer 110 of the specific embodiment of the microfluidic cartridge 100 functions preferably as described in Section 1.1, and is composed of polypropylene with low autofluorescence and a glass transition temperature suitable for PCR.”) • U.S. Patent No. 9,738,887 at 23:36-41 (“Each detection chamber 117 of the specific embodiment is identical and comprised of three interconnected channels, configured in a circular arrangement, with each of the interconnected channels approximately 0.4 mm deep and 1.6 mm wide at its widest point, resulting in a total volume of -10 mL for each detection chamber 117.”) • U.S. Patent No. 9,738,887 at 24:1-11 (“In the specific embodiment, the intermediate substrate 120 is composed of a polypropylene material to minimize cost and simplify assembly, and in the orientation shown in FIG. 11B, the top of the intermediate substrate 120 is 1.5 mm thick. The film layer 125, partially separating the intermediate substrate 120 from the top layer 110 is a polypropylene film with a nominal thickness of 50 microns. The film layer 125 is able to withstand temperatures of up to 95° C. encountered during fabrication and during an intended PCR procedure, while being thermally bondable to the top layer 110.”)
1(g)	[the microfluidic device comprises] a DNA manipulation zone within the DNA manipulation module and configured to perform PCR amplification of a sample;	<p>The accused system comprises a microfluidic device comprising a DNA manipulation zone within the DNA manipulation module and configured to perform PCR amplification of a sample.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that

Claim	Claim Language	Infringement Evidence
		<p>fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.”</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”  <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis,

Claim	Claim Language	Infringement Evidence
		<p>nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.”</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process

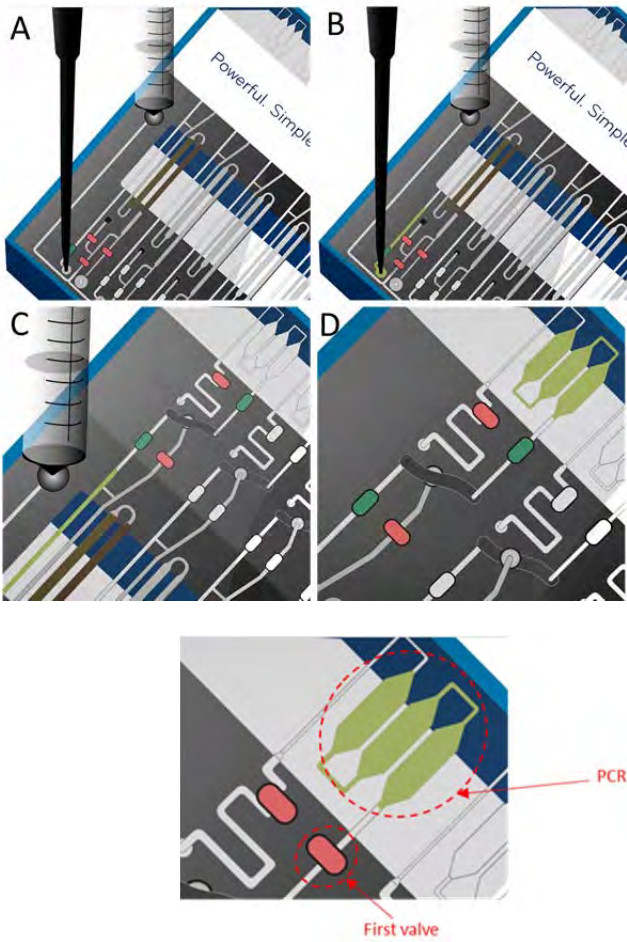
Claim	Claim Language	Infringement Evidence
		<p>begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p>  <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first

Claim	Claim Language	Infringement Evidence
		<p>sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <ul style="list-style-type: none"> • Claim 11. The cartridge of claim 10, further comprising 1) a heating region defined as a recessed region of the first layer that is parallel to the set of voids of the corrugated surface, and 2) a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample

Claim	Claim Language	Infringement Evidence
		<p>port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple

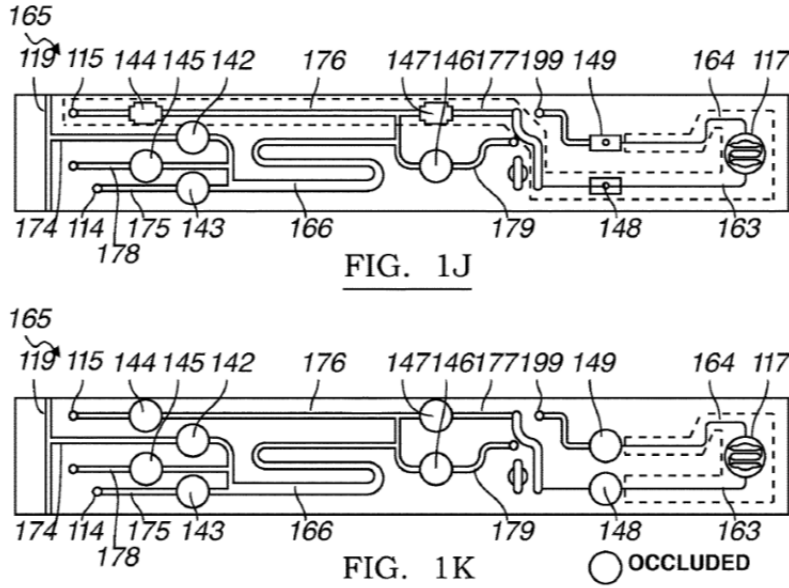
Claim	Claim Language	Infringement Evidence
		<p>wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:49-65 (“The cartridge heater 153 functions to

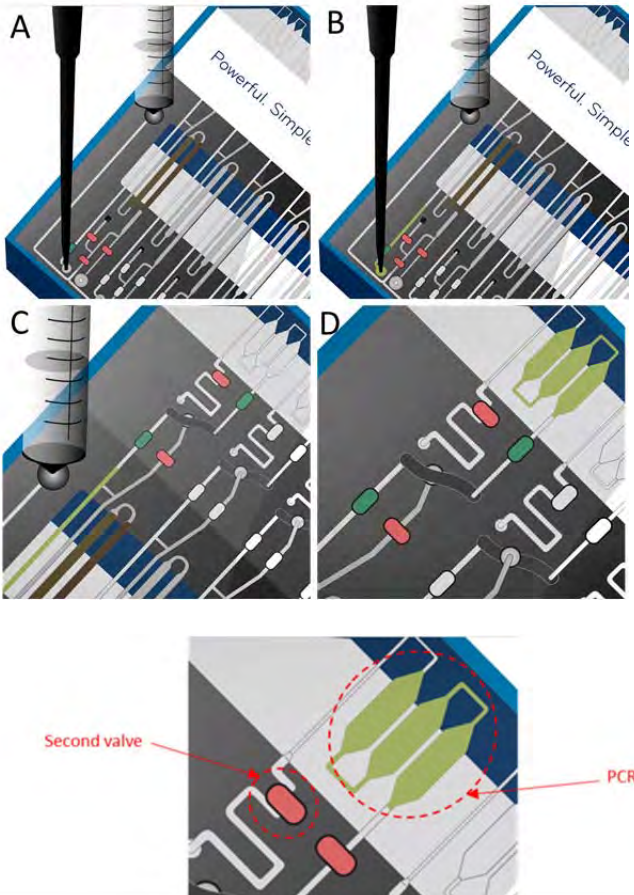
Claim	Claim Language	Infringement Evidence
		<p>transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224... The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 29:44-47 (“In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample.”)
1(h)	[the microfluidic device comprises] a first valve disposed within the DNA manipulation module upstream of the DNA manipulation zone;	<p>The accused system comprises a microfluidic device comprising a first valve disposed within the DNA manipulation module upstream of the DNA manipulation zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

Claim	Claim Language	Infringement Evidence
		 <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve

Claim	Claim Language	Infringement Evidence
		<p>guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as

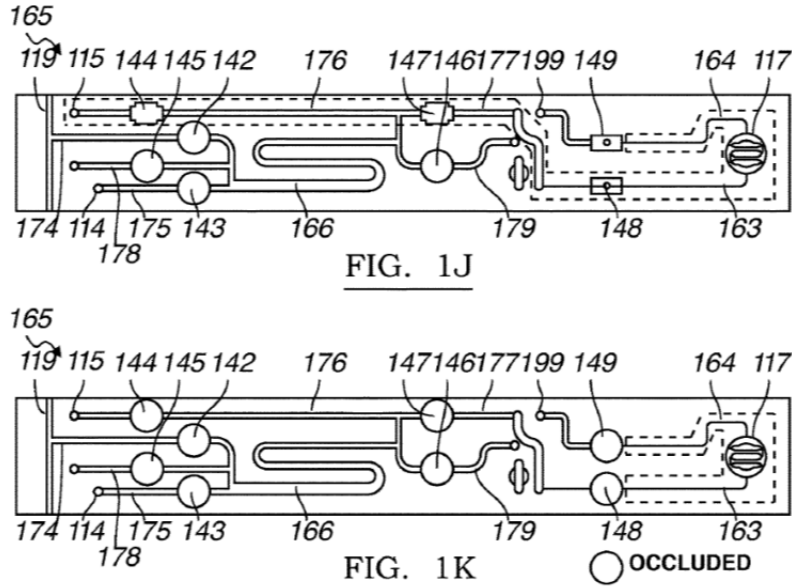
Claim	Claim Language	Infringement Evidence
		<p>shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)at Figs. 1J and 1K:</p>

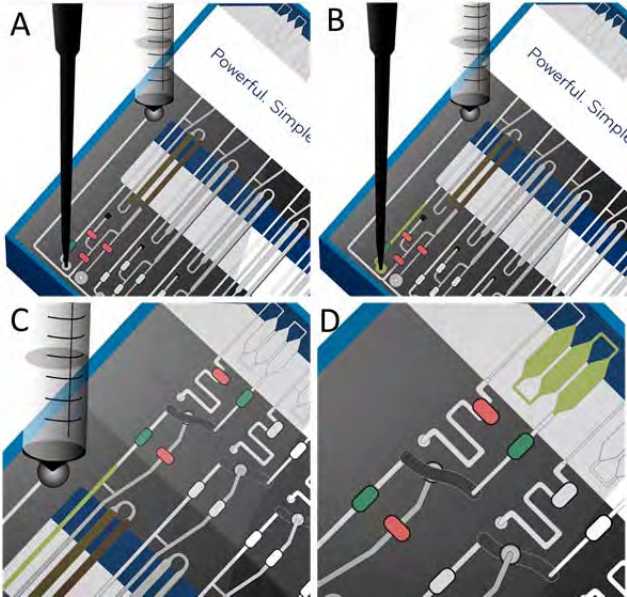
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1297 488 1430 521">FIG. 1J</p> <p data-bbox="1297 789 1430 821">FIG. 1K</p> <p data-bbox="1541 789 1703 821">○ OCCLUDED</p> <ul data-bbox="842 854 1913 1211" style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
1(i)	[the microfluidic device comprises] a second valve disposed within the DNA manipulation module	The accused system comprises a microfluidic device comprising a second valve disposed within the DNA manipulation module downstream of the DNA manipulation zone.

Claim	Claim Language	Infringement Evidence
	downstream of the DNA manipulation zone; and	<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

Claim	Claim Language	Infringement Evidence
		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second

Claim	Claim Language	Infringement Evidence
		<p>truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)at Figs. 1J and 1K:

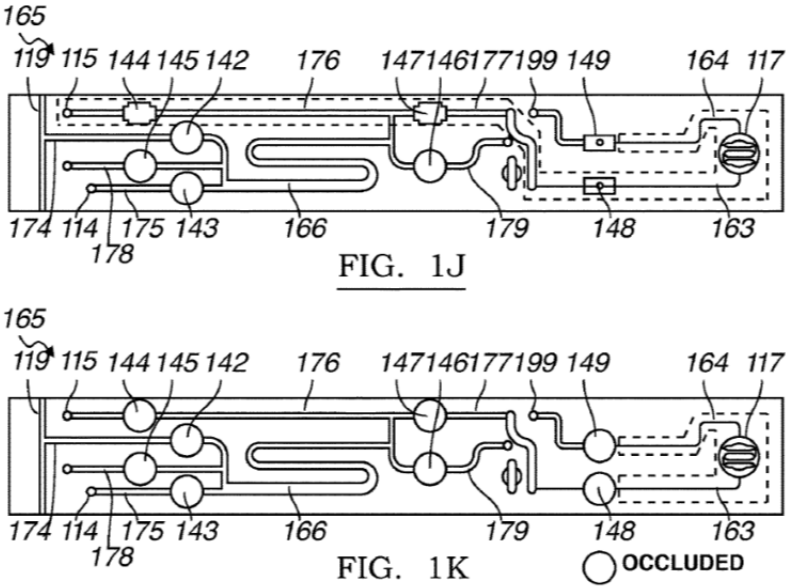
Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
1(j)	[the microfluidic device comprises] a vent disposed within the DNA manipulation module and separated from the upstream channel by the first and second valves.	The accused system comprises a microfluidic device comprising a vent disposed within the DNA manipulation module and separated from the upstream channel by the first and second valves.

Claim	Claim Language	Infringement Evidence
	upstream channel by the first and second valves;	<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>  <p>On information and belief, the accused cartridge comprises a vent disposed within the DNA manipulation module and separated from the upstream channel by the first and second valves.</p> <ul style="list-style-type: none"> • <i>Id.</i> at 2:10

Claim	Claim Language	Infringement Evidence
		<div data-bbox="793 245 1787 802" data-label="Image"> <p>The image shows a top-down view of a cartridge assembly. A series of red arrows, all originating from a single point labeled 'Vents' in red text, point to a row of small circular openings along the top edge of a dark, rectangular component. To the right of this main component, a dashed green rectangular box highlights a separate section. Within this boxed area, a small circular feature is circled with a red dashed line.</p> </div> <p data-bbox="793 841 1115 873">US9101930 (Exhibit 25)</p> <ul data-bbox="842 881 1921 1425" style="list-style-type: none"> • Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate. • Claim 11. The cartridge of claim 10, wherein the first layer is a unitary

Claim	Claim Language	Infringement Evidence
		<p>construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, wherein the first fluidic pathway is substantially identical to the second fluidic pathway, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <ul style="list-style-type: none"> • Claim 13. The cartridge of claim 11, further comprising a heating region as a recessed region of the first layer that is parallel to the set of parallel voids of the corrugated surface, and a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. • Claim 15. The cartridge of claim 13, wherein at least of the first fluidic pathway and the second fluidic pathway is coupled to an end vent configured to provide fine metering of fluid flow. <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent

Claim	Claim Language	Infringement Evidence
		<p>port, the fluid port, and the detection chamber.</p> <ul style="list-style-type: none"> • Claim 10. The cartridge of claim 1, wherein a terminal portion of the fluidic pathway is coupled to an end vent, configured to provide fine metering of fluid flow. • U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) • U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> U.S. Patent No. 8,738,887 at 15:4-6 (“A fluidic pathway 165 may also further comprise an end vent 199, which functions to prevent any fluid from escaping the microfluidic channel.”)
1(k)	a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone when amplification of the sample occurs,	<p>The accused system comprises a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone when amplification of the sample occurs.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that

Claim	Claim Language	Infringement Evidence
		<p>fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

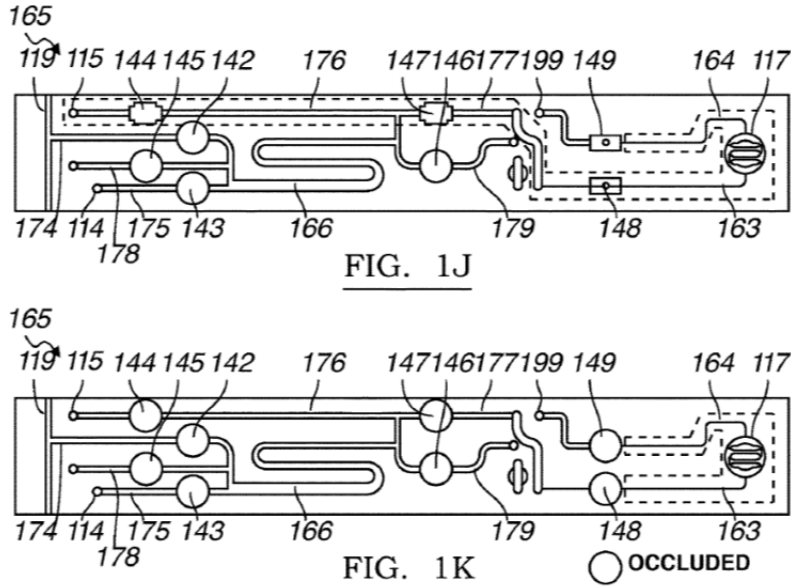
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads. • Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic

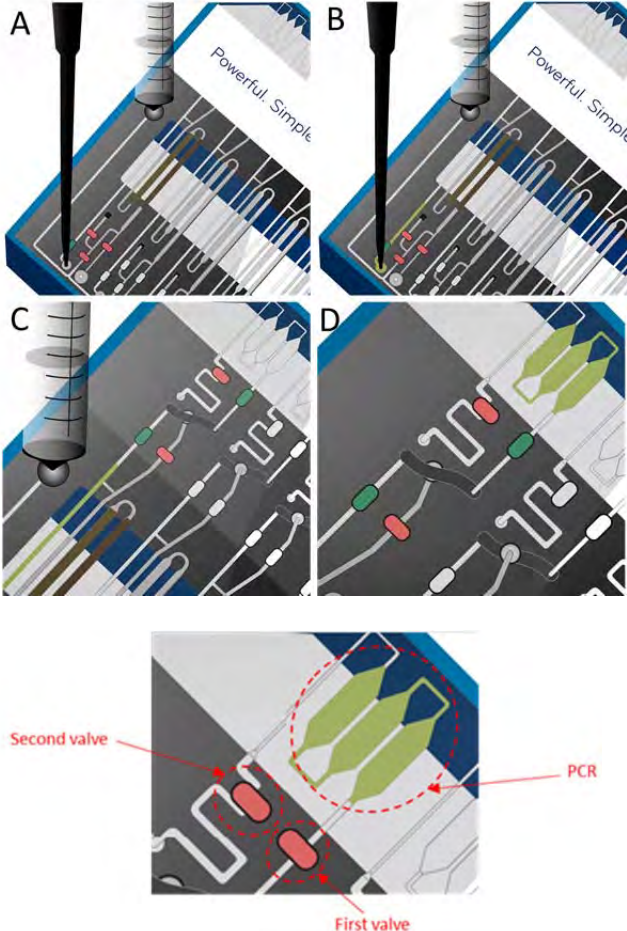
Claim	Claim Language	Infringement Evidence
		<p>pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,339,812 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,339,812 at 3:41-46 (“The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”) • U.S. Patent No. 9,339,812 at 26:25-32 (“In a variation wherein the controller 272 is coupled to the molecular diagnostic module 130, the controller 272 preferably functions to automate reception of a microfluidic cartridge, heating of biological samples within the molecular diagnostic module 130 and the detection chambers 213, occlusion of fluidic pathways 220 by the valve actuation subsystem 170, and analysis of a set of nucleic acid-reagent mixtures by the optical subsystem 180.”) • U.S. Patent No. 9,339,812 at 33:3-39 (“Embodiments of the method 400 and

Claim	Claim Language	Infringement Evidence
		<p>variations thereof can be embodied and/or implemented at least in part by a machine configured to receive a computer-readable medium storing computer-readable instructions. The instructions are preferably executed by computer-executable components preferably integrated with the system 100 and one or more portions of the processor 273 and/or the controller 272. The computer-readable medium can be stored on any suitable computer-readable media such as RAMs, ROMs, flash memory, EEPROMs, optical devices (CD or DVD), hard drives, floppy drives, or any suitable device. The computer-executable component is preferably a general or application specific processor, but any suitable dedicated hardware or hardware/firmware combination device can alternatively or additionally execute the instructions. The FIGURES illustrate the architecture, functionality and operation of possible implementations of systems, methods and computer program products according to preferred embodiments, example configurations, and variations thereof. In this regard, each block in the flowchart or block diagrams may represent a module, segment, or portion of code, which comprises one or more executable instructions for implementing the specified logical function(s). It should also be noted that, in some alternative implementations, the functions noted in the block can occur out of the order noted in the FIGURES. For example, two blocks shown in succession may, in fact, be executed substantially concurrently, or the blocks may sometimes be executed in the reverse order, depending upon the functionality involved. It will also be noted that each block of the block diagrams and/or flowchart illustration, and combinations of blocks in the block diagrams and/or flowchart illustration, can be implemented by special purpose hardware-based systems that perform the specified functions or acts, or combinations of special purpose hardware and computer instructions.”)</p> <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated

Claim	Claim Language	Infringement Evidence
		<p>surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 12:11-19 (“When not in operation, however, the normally closed position 43 is configured to prevent leakage and/or fluid

Claim	Claim Language	Infringement Evidence
		<p>bypass. The normally closed position may also be held closed by an occluding object, to prevent leakage even under pressure provided by a fluid delivery system, or under pressure experienced during a high temperature step (e.g., thermocycling) to prevent evaporation of a sample undergoing thermocycling.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) US Patent No. 9,738,887 at Figs. 1J and 1K:

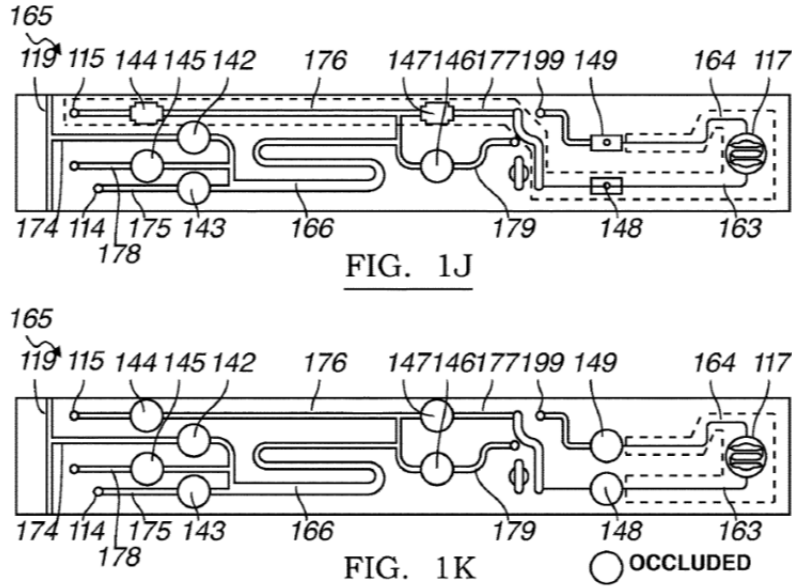
Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
1(l)	wherein the only ingress to and egress from the DNA manipulation zone is through the first and second valves, and	<p>In the accused system, the only ingress to and egress from the DNA manipulation zone is through the first and second valves.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6,</p>

Claim	Claim Language	Infringement Evidence
		<p>2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

Claim	Claim Language	Infringement Evidence
		<p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads. Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber.

Claim	Claim Language	Infringement Evidence
		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic

Claim	Claim Language	Infringement Evidence
		<p>pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
1(m)	wherein the computer-controlled heat source is in thermal contact with the DNA manipulation	In the accused system, the computer-controlled heat source is in thermal contact with the DNA manipulation zone.

Claim	Claim Language	Infringement Evidence
	zone; and	<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6,</p>

Claim	Claim Language	Infringement Evidence
		<p>2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, last visited May 31, 2019, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> • “There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.” • “The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first

Claim	Claim Language	Infringement Evidence
		<p>substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics

Claim	Claim Language	Infringement Evidence
		<p>substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,499,896 at 2:21-32 (“As shown in FIGS. 1A and 1B, an embodiment of a system 100 for thermocycling biological samples within detection chambers comprises: a set of heater-sensor dies 110; an electronics substrate 140 that couple the set of heater-sensor dies to a controller; a set of heat sink supports 150 coupled to at least one of the electronics substrate and the set of heater-sensor dies; and a set of elastic elements 160 coupled to the electronics substrate and configured to bias each of the set of heater-sensor dies against a detection 30 chamber. In some embodiments, the system 100 further comprises a controller 165 and/or a cooling subsystem 170 configured to actively cool the system 100.”) • U.S. Patent No. 9,499,896 at 9:11-19 (“As shown in FIGS. 1, 4A-4B, and 7A-7C, the system 100 can further comprise an electronics substrate 140 configured to couple heating and sensing elements of the set of heater-sensor dies to a controller 165, a set of heat-sink supports 150 configured to facilitate heat dissipation within the system 100, a set of elastic elements 160 configured to bias the set of heater-sensor dies 110 against detection chambers for sample processing, and can additionally comprise the controller 165 and/or a cooling subsystem 170.”) • U.S. Patent No. 9,499,896 at 12:20-31 (“In a specific example, the controller 165 comprises a Yokogawa UT750 PID controller, an Arduino UNO R3 microcontroller configured to cycle the UT750 through temperature stages and to control temperature holding, a resistance-to-voltage conversion circuit, and two power supplies—a first power supply configured to supply power to the set of heater-sensor dies 110 and a second power supply

Claim	Claim Language	Infringement Evidence
		<p>configured to supply voltage to the resistance-to-voltage conversion circuit. In the specific example, the controller 165 comprises a resistance-to-voltage conversion circuit because the UT750 PID controller requires voltage as an input for PID control.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 11:63-12:4 “As shown in FIGS. 1A and 1B, the system 100 can further comprise a controller 165, which functions to automate and/or control heating parameters provided by the set of heater-sensor dies 110. The controller 165 can further be configured to provide heat parameter output commands to the heating element(s) 114, and/or configured to receive communication of heating parameters (e.g., detected temperatures) sensed at the sensing element(s) 115 of the system 100.”
1(n)	wherein the detector is configured to identify one or more polynucleotides within the DNA manipulation zone.	<p>The accused system comprises a detector configured to identify one or more polynucleotides within the DNA manipulation zone.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/product/neumodx-288/, last visited June 3, 2019 (Exhibit 13)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/product/neumodx-96/, last visited June 3, 2019 (Exhibit 14)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p>JFO_2018-10-25_8009-Rev-B_NeuMoDx-96-Spec-Sheet (Exhibit 21)</p>


Claim	Claim Language	Infringement Evidence																																				
		<table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>NeuMoDx_288_Spec_Sheet_R2.pdf (Exhibit 22)</p> <table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>US10041062 (Exhibit 33)</p> <ul style="list-style-type: none"> Claim 1. A molecular diagnostic system configured to process a biological sample within a cartridge and separate a nucleic acid volume from the biological sample, the molecular diagnostic system comprising: a cartridge platform that supports the cartridge and comprising a magnet receiving slot configured to be aligned with the cartridge in a first operation mode; a nozzle of a liquid handling subsystem; an optical subsystem; a cartridge heater; a magnet vertically aligned with the magnet receiving slot; and an actuator coupled to the nozzle of the liquid handling subsystem, the optical subsystem, and the cartridge heater, the actuator configured to vertically displace the cartridge platform in the first operation mode to a position wherein: the nozzle of the liquid handling system is coupled to a fluid port of the cartridge, wherein the fluid port of the cartridge receives fluids for processing the biological sample, the magnet passes through the magnet receiving slot of the cartridge platform and interfaces with a first portion of the cartridge, the optical subsystem interfaces with a second portion 	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass
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		<p>of the cartridge, wherein the second portion of the cartridge receives a processed derivative of the nucleic acid volume, and a third region of the cartridge is compressed between the cartridge heater and the cartridge platform.</p> <ul style="list-style-type: none"> • Claim 8. The system of claim 1, wherein the optical subsystem comprises at least one unit including an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the biological sample, and to transmit emitted light from the biological sample, through the emission filter, and toward the photodetector. <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater. • Claim 11. The system of claim 1, wherein the molecular diagnostic module further comprises an optical subsystem comprising a first unit and a second unit, wherein each of the first unit and the second unit includes a set of excitation filters, a set of emission filters, a set of photodetectors aligned

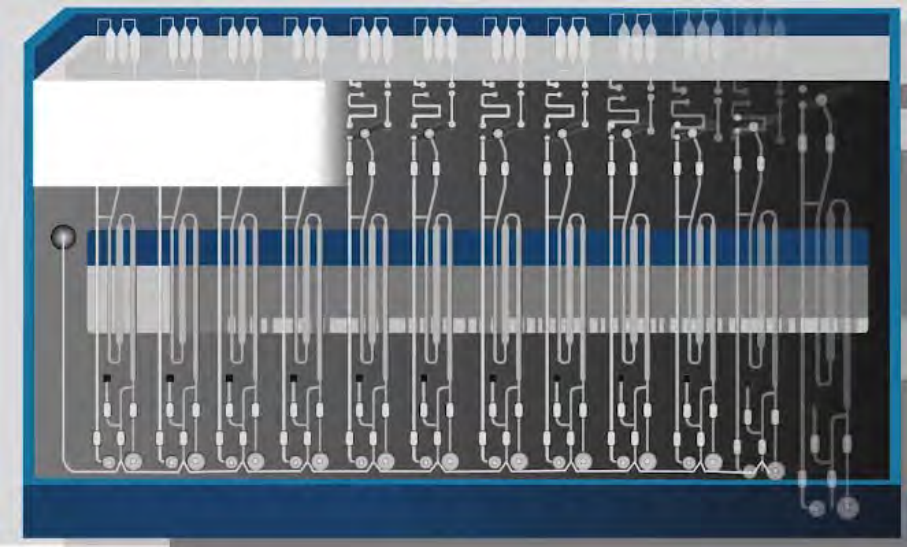
Claim	Claim Language	Infringement Evidence
		<p>with the set of emission filters, and a set of dichroic mirrors configured to reflect light from the set of excitation filters toward one of a set of nucleic acid-reagent mixtures at the cartridge, and to transmit emitted light from one of the set of nucleic acid-reagent mixtures, through at least one of the set of emission filters, and toward at least one of the set of photodetectors.</p> <ul style="list-style-type: none"> Claim 12. The system of claim 11, wherein the molecular diagnostic module further includes a set of detection chamber heaters configured to heat a set of detection chambers through the second surface of the cartridge, and wherein the optical subsystem is configured to receive light, emitted from the set of nucleic acid-reagent mixtures at the set of detection chambers, from the first surface of the cartridge.
18(a)	A device, comprising:	<p>To the extent the preamble is limiting, the accused instrument is a device.</p> <p><i>NeuMoDxTM Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p>

Claim	Claim Language	Infringement Evidence
		<div data-bbox="793 233 1845 1040" data-label="Image"> </div> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result”

Claim	Claim Language	Infringement Evidence
		<p>platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.”</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “NeuMoDx™ Molecular Systems are versatile; in addition to IVD tests, our system can also be used as an open system to process Laboratory Developed Tests (LDTs) that have been created and validated by your lab.” <p><i>NeuMoDx™ Molecular Systems, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, last visited May 31, 2019, hyperlink at</i></p>

Claim	Claim Language	Infringement Evidence
		<p>https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> “There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”
18(b)	a microfluidic process module;	<p>The accused device comprises a microfluidic process module</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”  <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic

Claim	Claim Language	Infringement Evidence
		<p>cartridge.”</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 24, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from ‘sample to result’. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>0600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • “NeuMoDx™ RELEASE Solution INSTRUCTIONS FOR USE... The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) and the dried Master Mix contained in a NeuMoDx test strip. The System then dispenses the prepared RT-PCR-ready mixture into the NeuMoDx

Claim	Claim Language	Infringement Evidence
		<p>Cartridge where Real-Time PCR occurs.”</p> <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59 

Claim	Claim Language	Infringement Evidence
		<p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater.
18(c)	a computer-controlled heat source; and	<p>The accused device comprises a computer-controlled heat source.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”.

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		<p>The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p>US9539576 (Exhibit 29)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points. <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating


Claim	Claim Language	Infringement Evidence
		<p>layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,499,896 at 2:21-32 (“As shown in FIGS. 1A and 1B, an embodiment of a system 100 for thermocycling biological samples within detection chambers comprises: a set of heater-sensor dies 110; an electronics substrate 140 that couple the set of heater-sensor dies to a controller; a set of heat sink supports 150 coupled to at least one of the electronics substrate and the set of heater-sensor dies; and a set of elastic elements 160 coupled to the electronics substrate and configured to bias each of the set of heater-sensor dies against a detection 30 chamber. In some embodiments, the system 100 further comprises a controller 165 and/or a cooling subsystem 170 configured to actively cool the system 100.”) • U.S. Patent No. 9,499,896 at 9:11-19 (“As shown in FIGS. 1, 4A-4B, and 7A-7C, the system 100 can further comprise an electronics substrate 140 configured to couple heating and sensing elements of the set of heater-sensor dies to a controller 165, a set of heat-sink supports 150 configured to facilitate heat dissipation within the system 100, a set of elastic elements 160

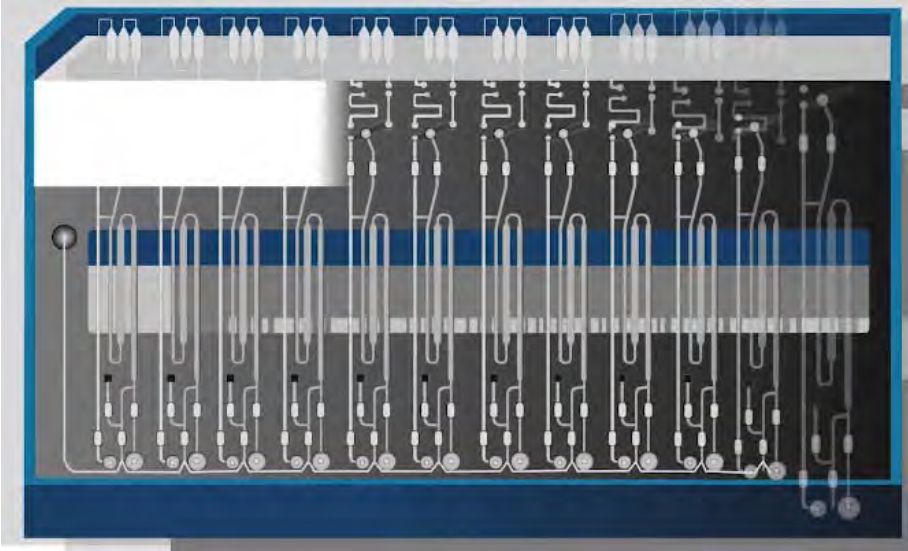
Claim	Claim Language	Infringement Evidence
		<p>configured to bias the set of heater-sensor dies 110 against detection chambers for sample processing, and can additionally comprise the controller 165 and/or a cooling subsystem 170.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 12:20-31 (“In a specific example, the controller 165 comprises a Yokogawa UT750 PID controller, an Arduino UNO R3 microcontroller configured to cycle the UT750 through temperature stages and to control temperature holding, a resistance-to-voltage conversion circuit, and two power supplies—a first power supply configured to supply power to the set of heater-sensor dies 110 and a second power supply configured to supply voltage to the resistance-to-voltage conversion circuit. In the specific example, the controller 165 comprises a resistance-to-voltage conversion circuit because the UT750 PID controller requires voltage as an input for PID control.”) U.S. Patent No. 9,499,896 at 11:63-12:4 “As shown in FIGS. 1A and 1B, the system 100 can further comprise a controller 165, which functions to automate and/or control heating parameters provided by the set of heater-sensor dies 110. The controller 165 can further be configured to provide heat parameter output commands to the heating element(s) 114, and/or configured to receive communication of heating parameters (e.g., detected temperatures) sensed at the sensing element(s) 115 of the system 100.”
18(d)	a detector;	<p>The accused device comprises a detector.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/product/neumodx-288/, last visited June 3, 2019 (Exhibit 13)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/product/neumodx-96/, last visited June 3, 2019 (Exhibit 14)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of

Claim	Claim Language	Infringement Evidence																																				
		<p>products of amplification.”</p> <p>JFO_2018-10-25_8009-Rev-B_NeuMoDx-96-Spec-Sheet (Exhibit 21)</p> <table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>NeuMoDx 288 Spec Sheet R2.pdf (Exhibit 22)</p> <table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>US10041062 (Exhibit 33)</p> <ul style="list-style-type: none"> Claim 1. A molecular diagnostic system configured to process a biological sample within a cartridge and separate a nucleic acid volume from the biological sample, the molecular diagnostic system comprising: a cartridge platform that supports the cartridge and comprising a magnet receiving slot configured to be aligned with the cartridge in a first operation mode; a nozzle of a liquid handling subsystem; an optical subsystem; a cartridge heater; a magnet vertically aligned with the magnet receiving slot; and an actuator coupled to the nozzle of the liquid handling subsystem, the optical subsystem, and the cartridge heater, the actuator configured to vertically displace the cartridge platform in the first operation mode to a position wherein: the nozzle of the liquid handling system is 	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass
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Claim	Claim Language	Infringement Evidence
		<p>coupled to a fluid port of the cartridge, wherein the fluid port of the cartridge receives fluids for processing the biological sample, the magnet passes through the magnet receiving slot of the cartridge platform and interfaces with a first portion of the cartridge, the optical subsystem interfaces with a second portion of the cartridge, wherein the second portion of the cartridge receives a processed derivative of the nucleic acid volume, and a third region of the cartridge is compressed between the cartridge heater and the cartridge platform.</p> <ul style="list-style-type: none"> Claim 8. The system of claim 1, wherein the optical subsystem comprises at least one unit including an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the biological sample, and to transmit emitted light from the biological sample, through the emission filter, and toward the photodetector. <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 11. The system of claim 1, wherein the molecular diagnostic module further comprises an optical subsystem comprising a first unit and a second unit, wherein each of the first unit and the second unit includes a set of excitation filters, a set of emission filters, a set of photodetectors aligned with the set of emission filters, and a set of dichroic mirrors configured to reflect light from the set of excitation filters toward one of a set of nucleic acid-reagent mixtures at the cartridge, and to transmit emitted light from one of the set of nucleic acid-reagent mixtures, through at least one of the set of emission filters, and toward at least one of the set of photodetectors. Claim 12. The system of claim 11, wherein the molecular diagnostic module further includes a set of detection chamber heaters configured to heat a set of detection chambers through the second surface of the cartridge, and wherein the optical subsystem is configured to receive light, emitted from the set of nucleic acid-reagent mixtures at the set of detection chambers, from the first surface of the cartridge.
18(e)	wherein the microfluidic process module comprises: a zone configured to receive a sample and perform amplification of the sample;	<p>The accused device comprises a microfluidic process module comprising a zone configured to receive a sample and perform amplification of the sample.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a

Claim	Claim Language	Infringement Evidence
		<p>multi-sample microfluidic cartridge.”</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”  <p><i>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf</i> (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6,</p>

Claim	Claim Language	Infringement Evidence
		<p>2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 228 1612 574" data-label="Image"> </div> <p data-bbox="793 651 1113 683">US9403165 (Exhibit 27)</p> <ul data-bbox="842 691 1921 1421" style="list-style-type: none"> <li data-bbox="842 691 1921 1161">• Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. <li data-bbox="842 1169 1921 1421">• Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the

Claim	Claim Language	Infringement Evidence
		<p>second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <ul style="list-style-type: none"> • Claim 11. The cartridge of claim 10, further comprising 1) a heating region defined as a recessed region of the first layer that is parallel to the set of voids of the corrugated surface, and 2) a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the

Claim	Claim Language	Infringement Evidence
		<p>waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the

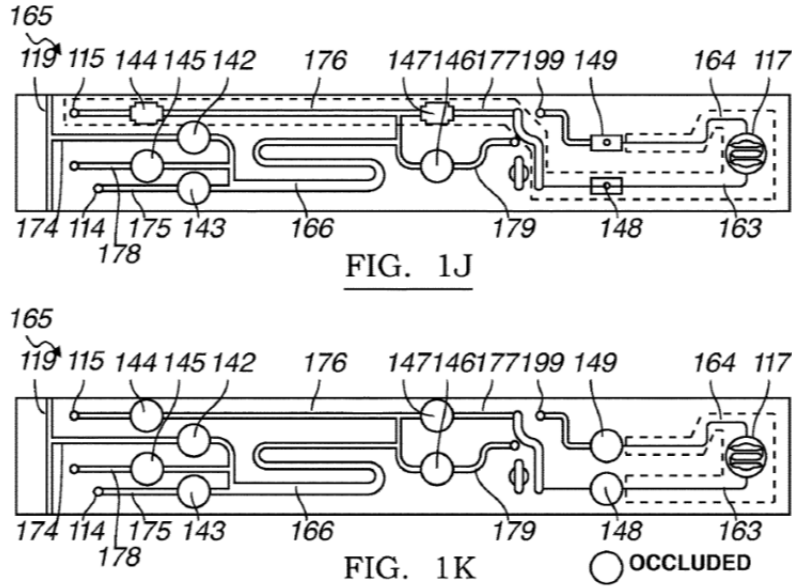
Claim	Claim Language	Infringement Evidence
		<p>detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) U.S. Patent No. 9,050,594 at 10:49-65 (“The cartridge heater 153 functions to transfer heat to a heating region 224 of a microfluidic cartridge 210, for inducing a pH shift to release bound nucleic acids from magnetic beads within the heating region 224... The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”)

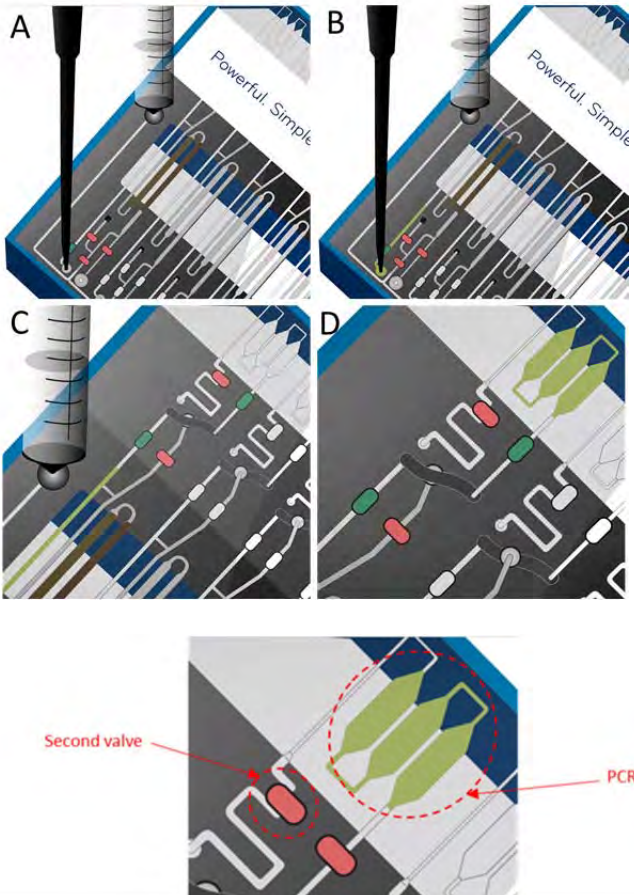
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 29:44-47 (“In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample.”)
18(f)	[the microfluidic process module comprises] a first valve upstream of the zone;	<p>The accused device comprises a microfluidic process module comprising a first valve upstream of the zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

Claim	Claim Language	Infringement Evidence
		 <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve

Claim	Claim Language	Infringement Evidence
		<p>guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as

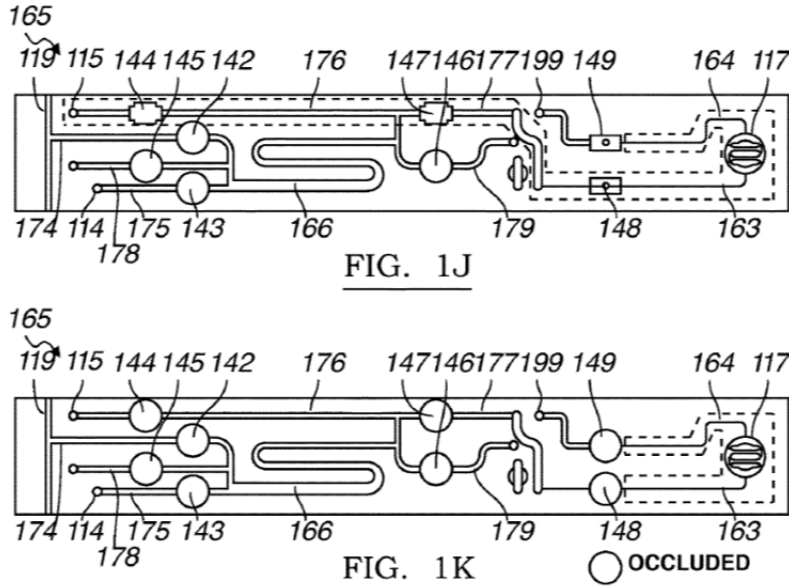
Claim	Claim Language	Infringement Evidence
		<p>shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

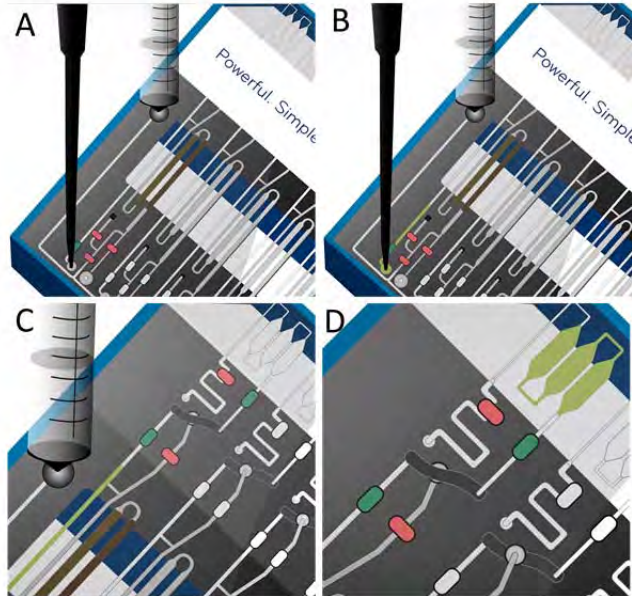
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1297 488 1430 521">FIG. 1J</p> <p data-bbox="1297 789 1430 821">FIG. 1K</p> <p data-bbox="1541 789 1709 821">○ OCCLUDED</p> <ul data-bbox="842 854 1919 1219" style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
18(g)	[the microfluidic process module comprises] a second valve downstream of the zone; and	The accused device comprises a microfluidic process module comprising a second valve downstream of the zone.

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

Claim	Claim Language	Infringement Evidence
		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second

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		<p>truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

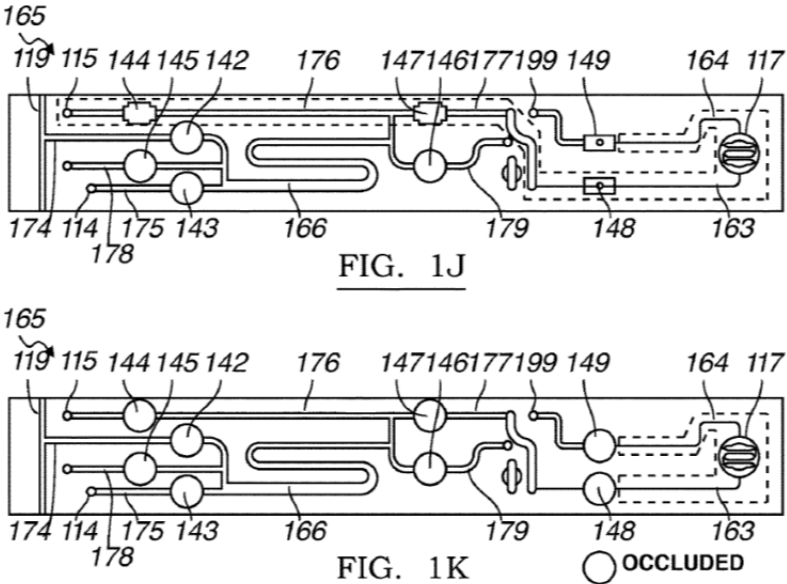
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1297 488 1430 521">FIG. 1J</p> <p data-bbox="1297 789 1430 821">FIG. 1K</p> <p data-bbox="1541 789 1703 821">○ OCCLUDED</p> <ul data-bbox="842 854 1923 1219" style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
18(h)	[the microfluidic process module comprises] a vent separated from the first valve by the second valve;	<p data-bbox="793 1260 1818 1325">The accused device comprises a microfluidic process module comprising a vent separated from the first valve by the second valve.</p> <p data-bbox="793 1365 1860 1398"><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6,</p>

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		<p data-bbox="793 233 1921 337">2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <div data-bbox="900 354 1528 946">  </div> <p data-bbox="842 987 1921 1091">On information and belief, the accused cartridge comprises a vent disposed within the DNA manipulation module and separated from the upstream channel by the first and second valves.</p> <ul data-bbox="842 1101 1024 1133" style="list-style-type: none"> • <i>Id.</i> at 2:10

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		<div data-bbox="793 245 1787 800" data-label="Image"> <p>The image shows a top-down view of a cartridge assembly. A series of red arrows, all originating from a single point labeled 'Vents' in red text, point to a row of small circular openings along the top edge of a dark, rectangular component. To the right of this main assembly, a dashed green rectangular box highlights a separate, smaller component. Within this dashed box, a small circular feature is circled with a red dashed line.</p> </div> <p>US9101930 (Exhibit 25)</p> <ul style="list-style-type: none"> Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate. Claim 11. The cartridge of claim 10, wherein the first layer is a unitary

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		<p>construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, wherein the first fluidic pathway is substantially identical to the second fluidic pathway, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <ul style="list-style-type: none"> • Claim 13. The cartridge of claim 11, further comprising a heating region as a recessed region of the first layer that is parallel to the set of parallel voids of the corrugated surface, and a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. • Claim 15. The cartridge of claim 13, wherein at least of the first fluidic pathway and the second fluidic pathway is coupled to an end vent configured to provide fine metering of fluid flow. <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent

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		<p>port, the fluid port, and the detection chamber.</p> <ul style="list-style-type: none"> • Claim 10. The cartridge of claim 1, wherein a terminal portion of the fluidic pathway is coupled to an end vent, configured to provide fine metering of fluid flow. • U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) • U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

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		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> U.S. Patent No. 8,738,887 at 15:4-6 (“A fluidic pathway 165 may also further comprise an end vent 199, which functions to prevent any fluid from escaping the microfluidic channel.”)
18(i)	a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the zone when amplification of the sample occurs in the zone,	<p>The accused device comprises a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the zone when amplification of the sample occurs in the zone</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that

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		<p>fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

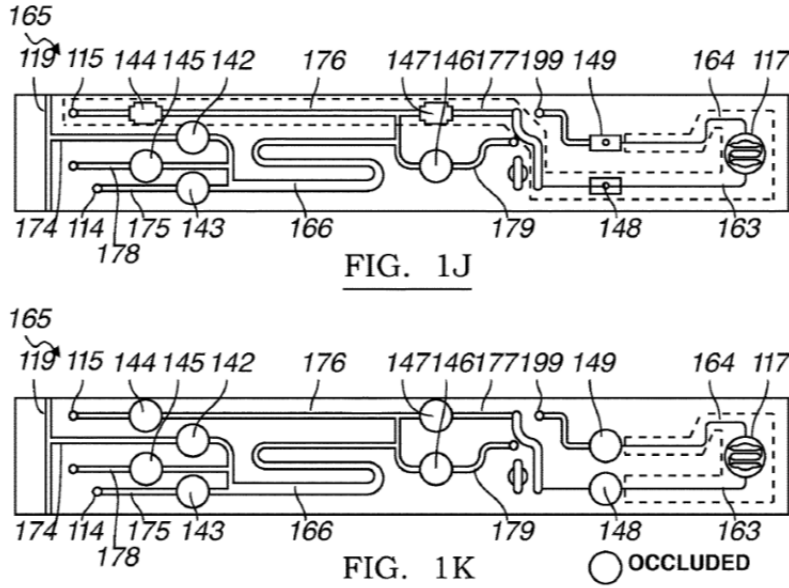
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		<ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads. • Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic

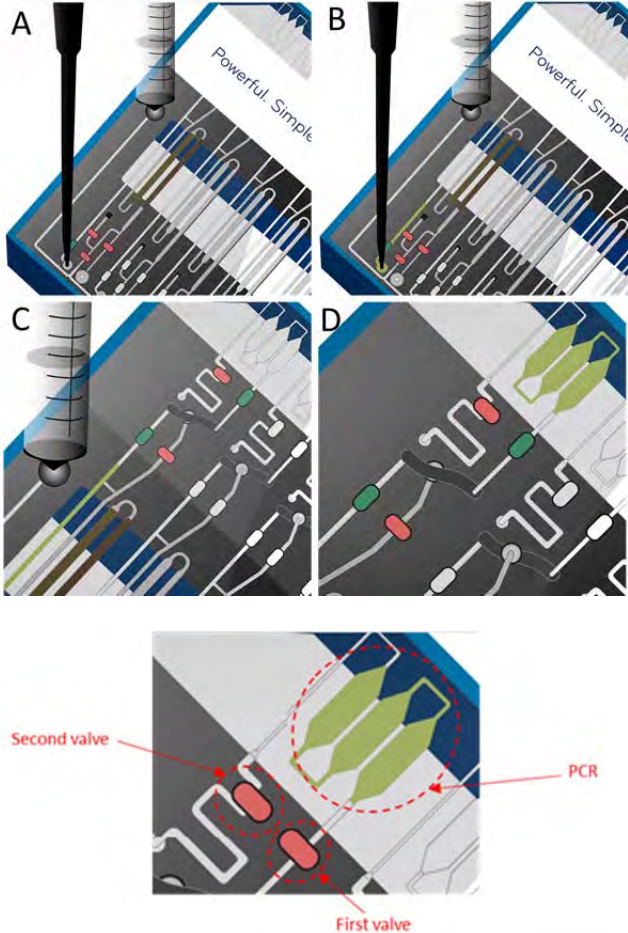
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		<p>pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,339,812 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,339,812 at 3:41-46 (“The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”) • U.S. Patent No. 9,339,812 at 26:25-32 (“In a variation wherein the controller 272 is coupled to the molecular diagnostic module 130, the controller 272 preferably functions to automate reception of a microfluidic cartridge, heating of biological samples within the molecular diagnostic module 130 and the detection chambers 213, occlusion of fluidic pathways 220 by the valve actuation subsystem 170, and analysis of a set of nucleic acid-reagent mixtures by the optical subsystem 180.”) • U.S. Patent No. 9,339,812 at 33:3-39 (“Embodiments of the method 400 and

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		<p>variations thereof can be embodied and/or implemented at least in part by a machine configured to receive a computer-readable medium storing computer-readable instructions. The instructions are preferably executed by computer-executable components preferably integrated with the system 100 and one or more portions of the processor 273 and/or the controller 272. The computer-readable medium can be stored on any suitable computer-readable media such as RAMs, ROMs, flash memory, EEPROMs, optical devices (CD or DVD), hard drives, floppy drives, or any suitable device. The computer-executable component is preferably a general or application specific processor, but any suitable dedicated hardware or hardware/firmware combination device can alternatively or additionally execute the instructions. The FIGURES illustrate the architecture, functionality and operation of possible implementations of systems, methods and computer program products according to preferred embodiments, example configurations, and variations thereof. In this regard, each block in the flowchart or block diagrams may represent a module, segment, or portion of code, which comprises one or more executable instructions for implementing the specified logical function(s). It should also be noted that, in some alternative implementations, the functions noted in the block can occur out of the order noted in the FIGURES. For example, two blocks shown in succession may, in fact, be executed substantially concurrently, or the blocks may sometimes be executed in the reverse order, depending upon the functionality involved. It will also be noted that each block of the block diagrams and/or flowchart illustration, and combinations of blocks in the block diagrams and/or flowchart illustration, can be implemented by special purpose hardware-based systems that perform the specified functions or acts, or combinations of special purpose hardware and computer instructions.”)</p> <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated

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		<p>surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 12:11-19 (“When not in operation, however, the normally closed position 43 is configured to prevent leakage and/or fluid

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		<p>bypass. The normally closed position may also be held closed by an occluding object, to prevent leakage even under pressure provided by a fluid delivery system, or under pressure experienced during a high temperature step (e.g., thermocycling) to prevent evaporation of a sample undergoing thermocycling.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) US Patent No. 9,738,887 at Figs. 1J and 1K:

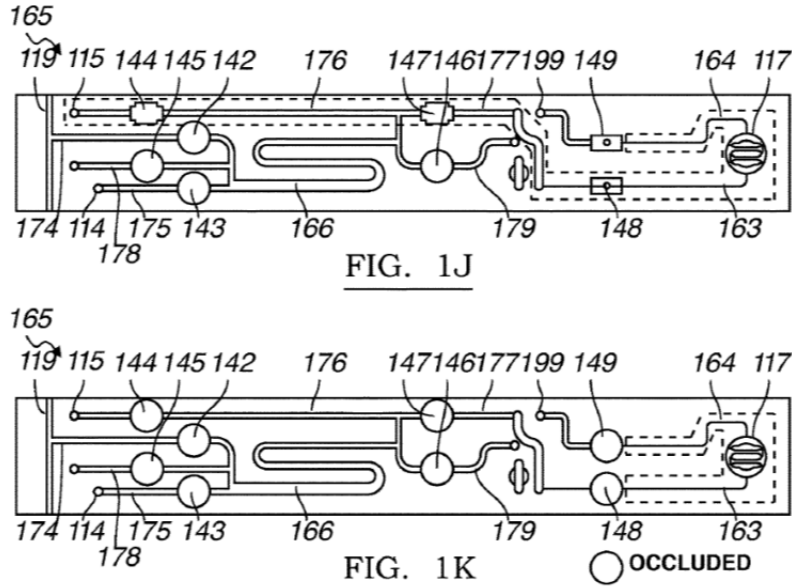
Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
18(j)	wherein the only ingress to and egress from the zone is through the first and second valves;	<p>In the accused device, the only ingress to and egress from the zone is through the first and second valves</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6,</p>

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		<p>2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08  <p>The image consists of four panels (A, B, C, D) showing a microfluidic cartridge being loaded with a pipette. Panel A shows the pipette tip at the inlet. Panel B shows the liquid being dispensed. Panel C shows the liquid filling the chamber. Panel D shows the liquid filling the chamber. Below these is a detailed view of the cartridge with labels: 'Second valve', 'First valve', and 'PCR'.</p>

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		<p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads. • Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber.

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		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic

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		<p>pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
18(k)	wherein the computer-controlled heat source is in thermal contact with the zone; and	<p>In the accused device, the computer-controlled heat source is in thermal contact with the zone.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/,</p>

Claim	Claim Language	Infringement Evidence
		<p>last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO </p>

Claim	Claim Language	Infringement Evidence
		<p>NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, last visited May 31, 2019, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> • “There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.” • “The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate

Claim	Claim Language	Infringement Evidence
		<p>connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the


Claim	Claim Language	Infringement Evidence
		<p>set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,499,896 at 2:21-32 (“As shown in FIGS. 1A and 1B, an embodiment of a system 100 for thermocycling biological samples within detection chambers comprises: a set of heater-sensor dies 110; an electronics substrate 140 that couple the set of heater-sensor dies to a controller; a set of heat sink supports 150 coupled to at least one of the electronics substrate and the set of heater-sensor dies; and a set of elastic elements 160 coupled to the electronics substrate and configured to bias each of the set of heater-sensor dies against a detection 30 chamber. In some embodiments, the system 100 further comprises a controller 165 and/or a cooling subsystem 170 configured to actively cool the system 100.”) • U.S. Patent No. 9,499,896 at 9:11-19 (“As shown in FIGS. 1, 4A-4B, and 7A-7C, the system 100 can further comprise an electronics substrate 140 configured to couple heating and sensing elements of the set of heater-sensor dies to a controller 165, a set of heat-sink supports 150 configured to facilitate heat dissipation within the system 100, a set of elastic elements 160 configured to bias the set of heater-sensor dies 110 against detection chambers for sample processing, and can additionally comprise the controller 165 and/or a cooling subsystem 170.”) • U.S. Patent No. 9,499,896 at 12:20-31 (“In a specific example, the controller 165 comprises a Yokogawa UT750 PID controller, an Arduino UNO R3 microcontroller configured to cycle the UT750 through temperature stages and to control temperature holding, a resistance-to-voltage conversion circuit, and two power supplies—a first power supply configured to supply power to the set of heater-sensor dies 110 and a second power supply configured to supply voltage to the resistance-to-voltage conversion circuit.

Claim	Claim Language	Infringement Evidence
		<p>In the specific example, the controller 165 comprises a resistance-to-voltage conversion circuit because the UT750 PID controller requires voltage as an input for PID control.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 11:63-12:4 “As shown in FIGS. 1A and 1B, the system 100 can further comprise a controller 165, which functions to automate and/or control heating parameters provided by the set of heater-sensor dies 110. The controller 165 can further be configured to provide heat parameter output commands to the heating element(s) 114, and/or configured to receive communication of heating parameters (e.g., detected temperatures) sensed at the sensing element(s) 115 of the system 100.”
18(l)	wherein the detector is configured to identify one or more polynucleotides within the zone.	<p>In the accused device, the detector is configured to identify one or more polynucleotides within the zone.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/product/neumodx-288/, last visited June 3, 2019 (Exhibit 13)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/product/neumodx-96/, last visited June 3, 2019 (Exhibit 14)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p>JFO_2018-10-25_8009-Rev-B_NeuMoDx-96-Spec-Sheet (Exhibit 21)</p>


Claim	Claim Language	Infringement Evidence																																				
		<table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>NeuMoDx_288_Spec_Sheet_R2.pdf (Exhibit 22)</p> <table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>US10041062 (Exhibit 33)</p> <ul style="list-style-type: none"> Claim 1. A molecular diagnostic system configured to process a biological sample within a cartridge and separate a nucleic acid volume from the biological sample, the molecular diagnostic system comprising: a cartridge platform that supports the cartridge and comprising a magnet receiving slot configured to be aligned with the cartridge in a first operation mode; a nozzle of a liquid handling subsystem; an optical subsystem; a cartridge heater; a magnet vertically aligned with the magnet receiving slot; and an actuator coupled to the nozzle of the liquid handling subsystem, the optical subsystem, and the cartridge heater, the actuator configured to vertically displace the cartridge platform in the first operation mode to a position wherein: the nozzle of the liquid handling system is coupled to a fluid port of the cartridge, wherein the fluid port of the cartridge receives fluids for processing the biological sample, the magnet passes through the magnet receiving slot of the cartridge platform and interfaces with a first portion of the cartridge, the optical subsystem interfaces with a second portion 	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass
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		<p>of the cartridge, wherein the second portion of the cartridge receives a processed derivative of the nucleic acid volume, and a third region of the cartridge is compressed between the cartridge heater and the cartridge platform.</p> <ul style="list-style-type: none"> Claim 8. The system of claim 1, wherein the optical subsystem comprises at least one unit including an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the biological sample, and to transmit emitted light from the biological sample, through the emission filter, and toward the photodetector. <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater. Claim 11. The system of claim 1, wherein the molecular diagnostic module further comprises an optical subsystem comprising a first unit and a second unit, wherein each of the first unit and the second unit includes a set of excitation filters, a set of emission filters, a set of photodetectors aligned

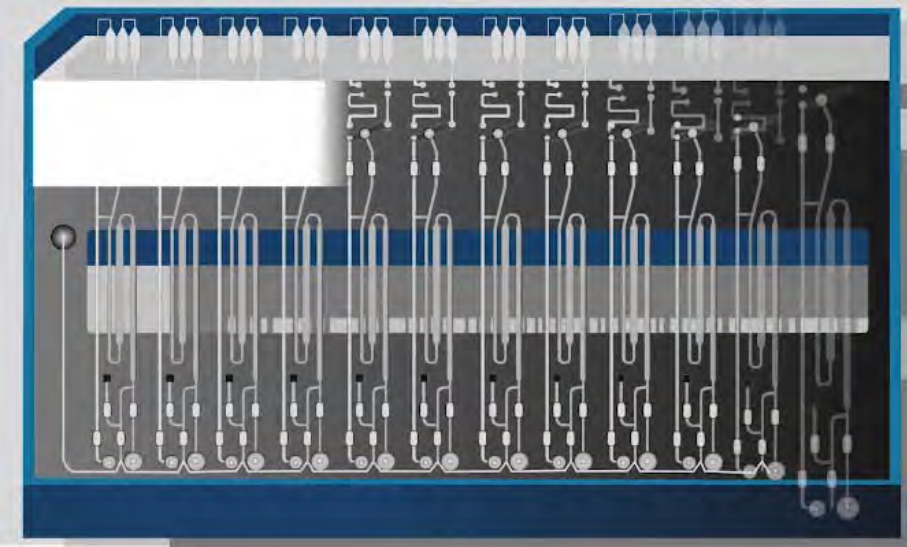
Claim	Claim Language	Infringement Evidence
		<p>with the set of emission filters, and a set of dichroic mirrors configured to reflect light from the set of excitation filters toward one of a set of nucleic acid-reagent mixtures at the cartridge, and to transmit emitted light from one of the set of nucleic acid-reagent mixtures, through at least one of the set of emission filters, and toward at least one of the set of photodetectors.</p> <ul style="list-style-type: none"> Claim 12. The system of claim 11, wherein the molecular diagnostic module further includes a set of detection chamber heaters configured to heat a set of detection chambers through the second surface of the cartridge, and wherein the optical subsystem is configured to receive light, emitted from the set of nucleic acid-reagent mixtures at the set of detection chambers, from the first surface of the cartridge.
19(a)	A system, comprising:	<p>To the extent the preamble is limiting, the accused instruments are a system.</p> <p><i>NeuMoDxTM Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p>

Claim	Claim Language	Infringement Evidence
		 <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result”

Claim	Claim Language	Infringement Evidence
		<p>platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.”</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “NeuMoDx™ Molecular Systems are versatile; in addition to IVD tests, our system can also be used as an open system to process Laboratory Developed Tests (LDTs) that have been created and validated by your lab.” <p><i>NeuMoDx™ Molecular Systems, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, last visited May 31, 2019, hyperlink at</i></p>

Claim	Claim Language	Infringement Evidence
		<p>https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> “There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”
19(b)	a microfluidic device;	<p>The accused system comprises a microfluidic device.</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”  <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic

Claim	Claim Language	Infringement Evidence
		<p>cartridge.”</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 24, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from ‘sample to result’. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>0600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • “NeuMoDx™ RELEASE Solution INSTRUCTIONS FOR USE... The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) and the dried Master Mix contained in a NeuMoDx test strip. The System then dispenses the prepared RT-PCR-ready mixture into the NeuMoDx

Claim	Claim Language	Infringement Evidence
		<p>Cartridge where Real-Time PCR occurs.”</p> <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59 

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		<p>US10041062 (Exhibit 33)</p> <ul style="list-style-type: none"> Claim 1. A molecular diagnostic system configured to process a biological sample within a cartridge and separate a nucleic acid volume from the biological sample, the molecular diagnostic system comprising: a cartridge platform that supports the cartridge and comprising a magnet receiving slot configured to be aligned with the cartridge in a first operation mode; a nozzle of a liquid handling subsystem; an optical subsystem; a cartridge heater; a magnet vertically aligned with the magnet receiving slot; and an actuator coupled to the nozzle of the liquid handling subsystem, the optical subsystem, and the cartridge heater, the actuator configured to vertically displace the cartridge platform in the first operation mode to a position wherein: the nozzle of the liquid handling system is coupled to a fluid port of the cartridge, wherein the fluid port of the cartridge receives fluids for processing the biological sample, the magnet passes through the magnet receiving slot of the cartridge platform and interfaces with a first portion of the cartridge, the optical subsystem interfaces with a second portion of the cartridge, wherein the second portion of the cartridge receives a processed derivative of the nucleic acid volume, and a third region of the cartridge is compressed between the cartridge heater and the cartridge platform. <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a

Claim	Claim Language	Infringement Evidence
		<p>magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater.</p>
19(c)	a computer-controlled heat source; and	<p>The accused system comprises a computer-controlled heat source.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and

Claim	Claim Language	Infringement Evidence
		<p>consumables.”</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the

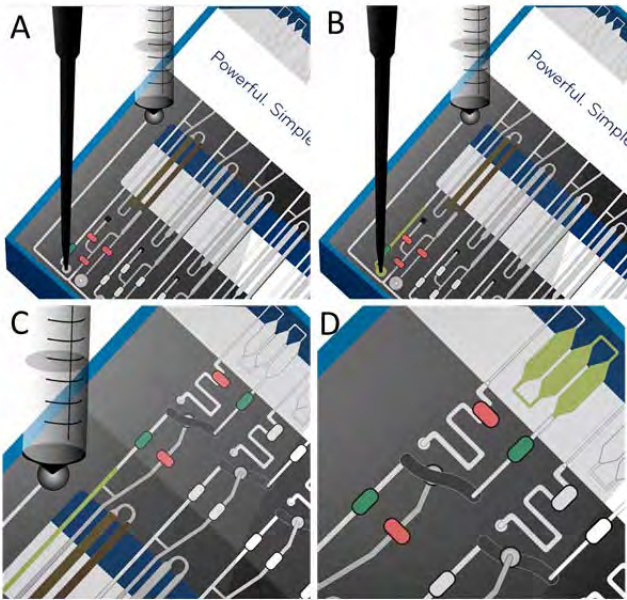
Claim	Claim Language	Infringement Evidence
		<p>second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first

Claim	Claim Language	Infringement Evidence
		<p>substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 2:21-32 (“As shown in FIGS. 1A and 1B, an embodiment of a system 100 for thermocycling biological samples within detection chambers comprises: a set of heater-sensor dies 110; an electronics substrate 140 that couple the set of heater-sensor dies to a controller; a set of heat sink supports 150 coupled to at least one of the electronics substrate and the set of heater-sensor dies; and a set of elastic elements 160 coupled to the electronics substrate and configured to bias each of the set of heater-sensor dies against a detection 30 chamber. In some embodiments, the system 100 further comprises a controller 165 and/or a cooling subsystem 170 configured to actively cool the system 100.”) U.S. Patent No. 9,499,896 at 9:11-19 (“As shown in FIGS. 1, 4A-4B, and 7A-7C, the system 100 can further comprise an electronics substrate 140 configured to couple heating and sensing elements of the set of heater-sensor dies to a controller 165, a set of heat-sink supports 150 configured to facilitate heat dissipation within the system 100, a set of elastic elements 160 configured to bias the set of heater-sensor dies 110 against detection chambers for sample processing, and can additionally comprise the controller 165 and/or a cooling subsystem 170.”) U.S. Patent No. 9,499,896 at 12:20-31 (“In a specific example, the controller 165 comprises a Yokogawa UT750 PID controller, an Arduino UNO R3 microcontroller configured to cycle the UT750 through temperature stages and to control temperature holding, a resistance-to-voltage conversion circuit, and two power supplies—a first power supply configured to supply power to the set of heater-sensor dies 110 and a second power supply configured to supply voltage to the resistance-to-voltage conversion circuit. In the specific example, the controller 165 comprises a resistance-to-voltage conversion circuit because the UT750 PID controller requires voltage as an

Claim	Claim Language	Infringement Evidence																		
		<p>input for PID control.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 11:63-12:4 “As shown in FIGS. 1A and 1B, the system 100 can further comprise a controller 165, which functions to automate and/or control heating parameters provided by the set of heater-sensor dies 110. The controller 165 can further be configured to provide heat parameter output commands to the heating element(s) 114, and/or configured to receive communication of heating parameters (e.g., detected temperatures) sensed at the sensing element(s) 115 of the system 100.” 																		
19(d)	a detector;	<p>The accused system comprises a detector</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/product/neumodx-288/, last visited June 3, 2019 (Exhibit 13)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/product/neumodx-96/, last visited June 3, 2019 (Exhibit 14)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p>JFO_2018-10-25_8009-Rev-B NeuMoDx-96-Spec-Sheet (Exhibit 21)</p> <table border="1"> <thead> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> </thead> <tbody> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </tbody> </table>	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass
Optical Wavelengths	Excitation (nm)	Emission (nm)																		
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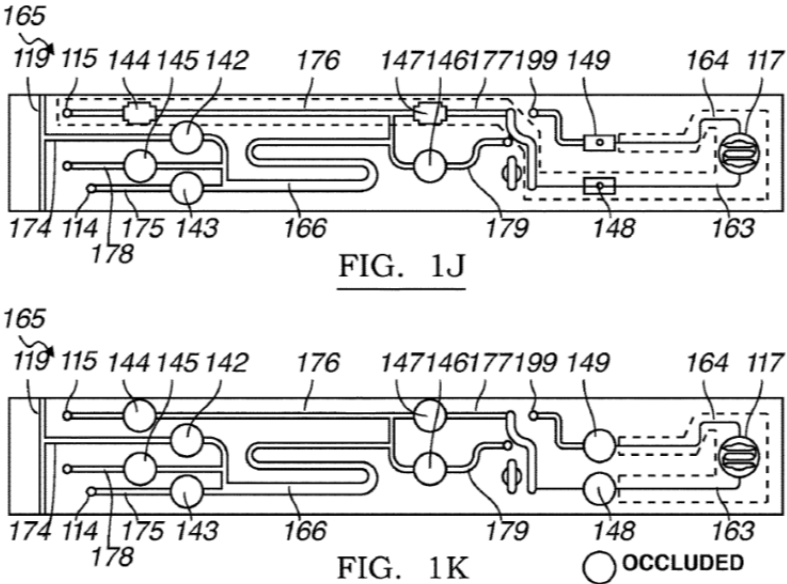
Claim	Claim Language	Infringement Evidence																		
		<p>NeuMoDx_288_Spec_Sheet_R2.pdf (Exhibit 22)</p> <table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>US10041062 (Exhibit 33)</p> <ul style="list-style-type: none"> Claim 1. A molecular diagnostic system configured to process a biological sample within a cartridge and separate a nucleic acid volume from the biological sample, the molecular diagnostic system comprising: a cartridge platform that supports the cartridge and comprising a magnet receiving slot configured to be aligned with the cartridge in a first operation mode; a nozzle of a liquid handling subsystem; an optical subsystem; a cartridge heater; a magnet vertically aligned with the magnet receiving slot; and an actuator coupled to the nozzle of the liquid handling subsystem, the optical subsystem, and the cartridge heater, the actuator configured to vertically displace the cartridge platform in the first operation mode to a position wherein: the nozzle of the liquid handling system is coupled to a fluid port of the cartridge, wherein the fluid port of the cartridge receives fluids for processing the biological sample, the magnet passes through the magnet receiving slot of the cartridge platform and interfaces with a first portion of the cartridge, the optical subsystem interfaces with a second portion of the cartridge, wherein the second portion of the cartridge receives a processed derivative of the nucleic acid volume, and a third region of the cartridge is compressed between the cartridge heater and the cartridge platform. Claim 8. The system of claim 1, wherein the optical subsystem comprises at least one unit including an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the biological sample, and to transmit emitted light from the biological sample, through 	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass
Optical Wavelengths	Excitation (nm)	Emission (nm)																		
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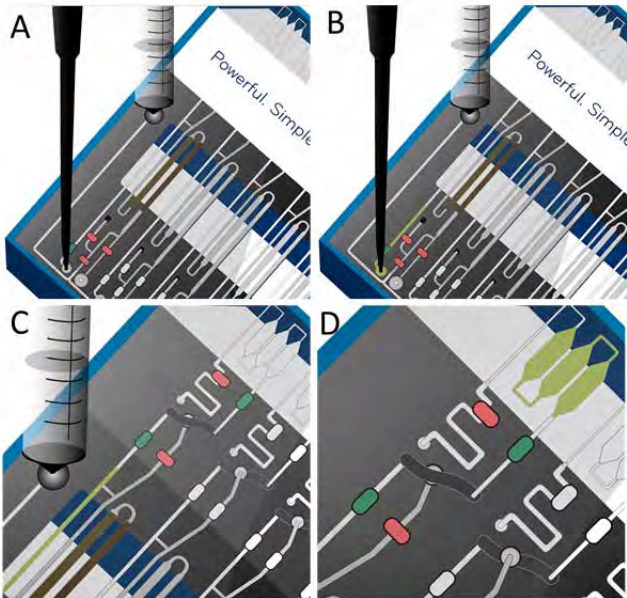
Claim	Claim Language	Infringement Evidence
		<p>the emission filter, and toward the photodetector.</p> <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater. • Claim 11. The system of claim 1, wherein the molecular diagnostic module further comprises an optical subsystem comprising a first unit and a second unit, wherein each of the first unit and the second unit includes a set of excitation filters, a set of emission filters, a set of photodetectors aligned with the set of emission filters, and a set of dichroic mirrors configured to reflect light from the set of excitation filters toward one of a set of nucleic acid-reagent mixtures at the cartridge, and to transmit emitted light from one of the set of nucleic acid-reagent mixtures, through at least one of the set of emission filters, and toward at least one of the set of photodetectors. • Claim 12. The system of claim 11, wherein the molecular diagnostic module further includes a set of detection chamber heaters configured to heat a set of detection chambers through the second surface of the cartridge, and wherein the

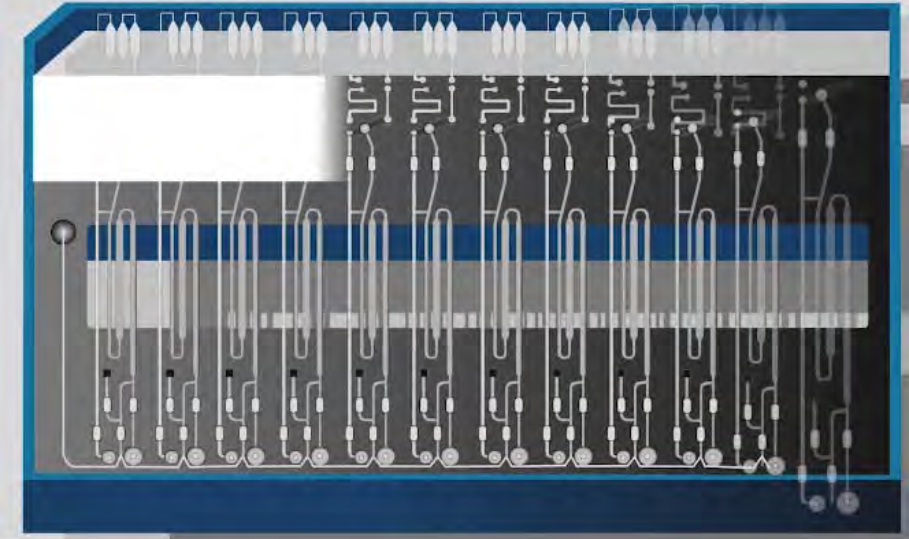
Claim	Claim Language	Infringement Evidence
		<p>optical subsystem is configured to receive light, emitted from the set of nucleic acid-reagent mixtures at the set of detection chambers, from the first surface of the cartridge.</p>
19(e)	wherein the microfluidic device comprises: an upstream channel;	<p>The accused system comprises a microfluidic device comprising an upstream channel</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08  <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to

Claim	Claim Language	Infringement Evidence
		<p>facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of Detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) • U.S. Patent No. 9,738,887 at 15:31-35 (“The segment running to a detection chamber 163 functions to deliver a processed sample fluid to the detection chamber 117 with a reduced quantity of gas bubbles, and the segment running away from the detection chamber 164 functions to deliver a fluid away from the detection chamber 117.”) • U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165

Claim	Claim Language	Infringement Evidence
		<p>may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

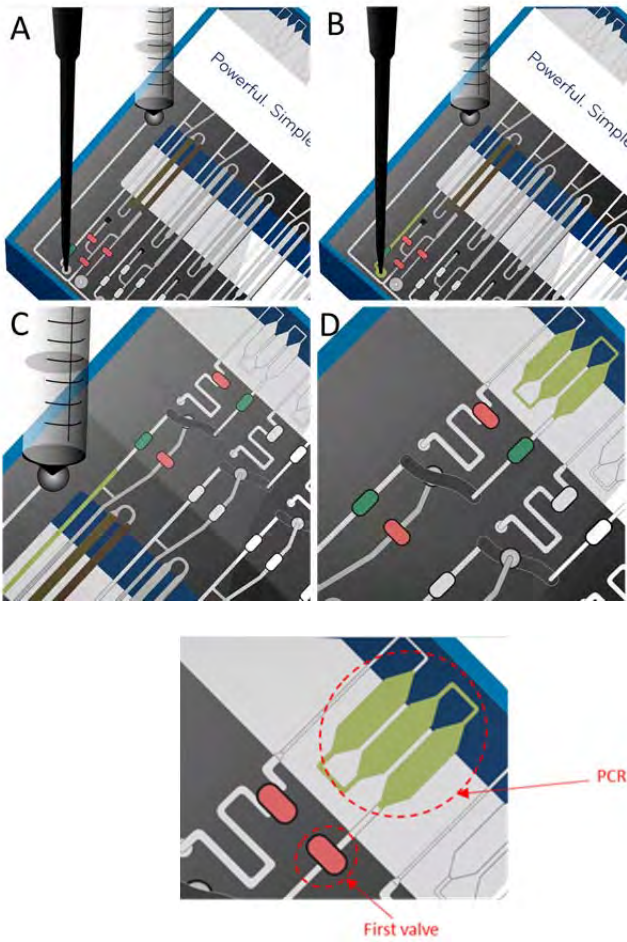
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 23:36-41 (“Each detection chamber 117 of the specific embodiment is identical and comprised of three interconnected channels, configured in a circular arrangement, with each of the interconnected channels approximately 0.4 mm deep and 1.6 mm wide at its widest point, resulting in a total volume of -10 mL for each detection chamber 117.”)
19(f)	[the microfluidic device comprises] a DNA manipulation zone located downstream from the upstream channel and configured to perform PCR amplification of a sample;	<p>The accused system comprises a microfluidic device comprising a DNA manipulation zone located downstream from the upstream channel and configured to perform PCR amplification of a sample</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

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		<ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08  <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.”

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		 <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 • U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of Detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”)

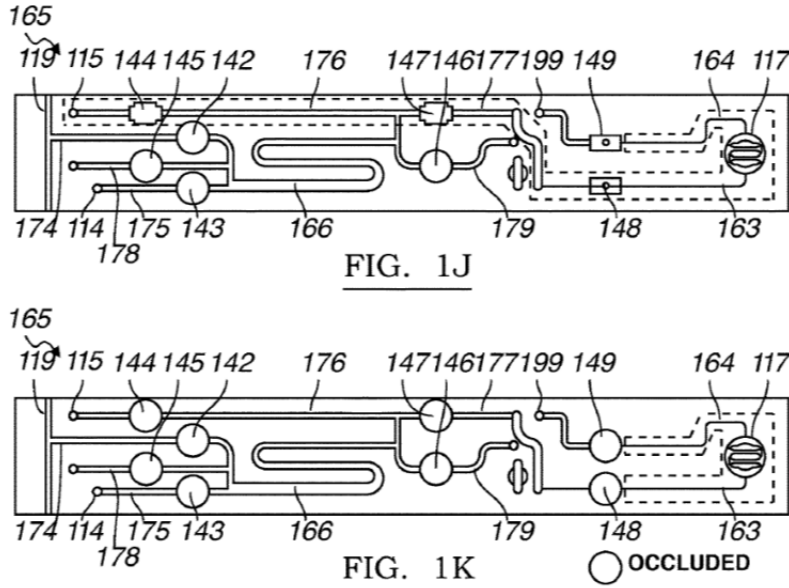
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 2:36-3:5. (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140.. In a specific application, the microfluidic cartridge 100 can be used to facilitate a PCR procedure for analysis of a sample containing nucleic acids.”) • U.S. Patent No. 9,738,887 at 13:7-18. (“The top layer 110 of an embodiment of the microfluidic cartridge 100 functions to accommodate elements involved in performing a molecular diagnostic procedure (e.g. PCR), such that a sample containing nucleic acids, passing through the cartridge, can be manipulated by the elements involved in performing the molecular diagnostic procedure. The top layer 110 is preferably composed of a structurally rigid/stiff material with low autofluorescence, such that the top layer 110 does not interfere with sample detection by fluorescence or chemiluminescence techniques, and an appropriate glass transition temperature and chemical compatibility for PCR or other amplification techniques.”) • U.S. Patent No. 9,738,887 at 13:35-42. (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) • U.S. Patent No. 9,738,887 at 15:29-39 (“The segments may be arranged in at least one of several configurations to facilitate isolation, processing, and

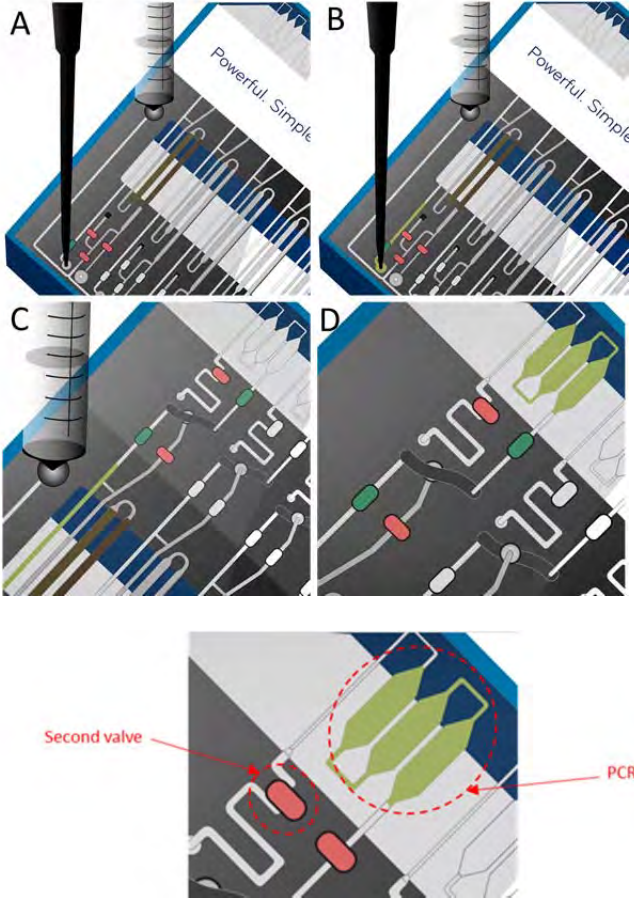
Claim	Claim Language	Infringement Evidence
		<p>amplification of a nucleic acid sample ...”).</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 23:20-24 (“The top layer 110 of the specific embodiment of the microfluidic cartridge 100 functions preferably as described in Section 1.1, and is composed of polypropylene with low autofluorescence and a glass transition temperature suitable for PCR.”) • U.S. Patent No. 9,738,887 at 23:36-41 (“Each detection chamber 117 of the specific embodiment is identical and comprised of three interconnected channels, configured in a circular arrangement, with each of the interconnected channels approximately 0.4 mm deep and 1.6 mm wide at its widest point, resulting in a total volume of -10 mL for each detection chamber 117.”) • U.S. Patent No. 9,738,887 at 24:1-11 (“In the specific embodiment, the intermediate substrate 120 is composed of a polypropylene material to minimize cost and simplify assembly, and in the orientation shown in FIG. 11B, the top of the intermediate substrate 120 is 1.5 mm thick. The film layer 125, partially separating the intermediate substrate 120 from the top layer 110 is a polypropylene film with a nominal thickness of 50 microns. The film layer 125 is able to withstand temperatures of up to 95° C. encountered during fabrication and during an intended PCR procedure, while being thermally bondable to the top layer 110.”)
19(g)	[the microfluidic device comprises] a first valve disposed upstream of the DNA manipulation zone; and	<p>The accused system comprises a microfluidic device comprising a first valve disposed upstream of the DNA manipulation zone</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

Claim	Claim Language	Infringement Evidence
		 <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve

Claim	Claim Language	Infringement Evidence
		<p>guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as

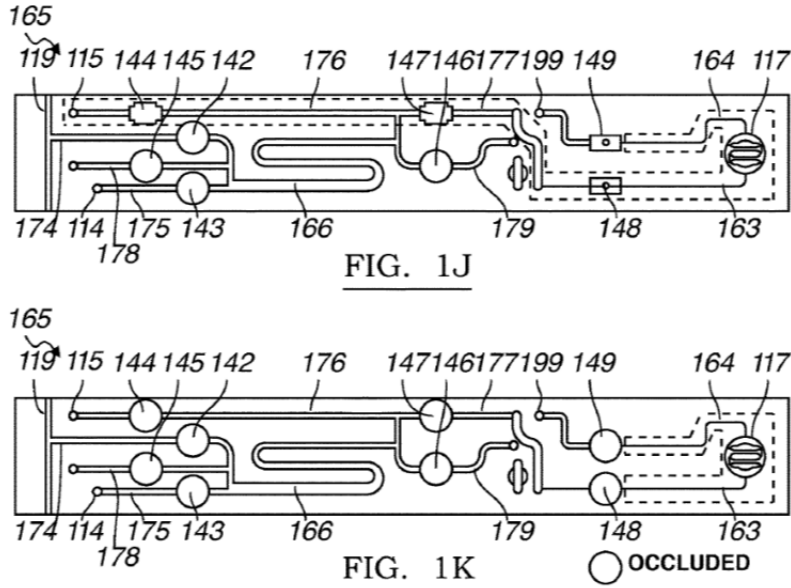
Claim	Claim Language	Infringement Evidence
		<p>shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)at Figs. 1J and 1K:</p>

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1297 488 1430 521">FIG. 1J</p> <p data-bbox="1297 792 1430 824">FIG. 1K</p> <p data-bbox="1541 792 1703 824">○ OCCLUDED</p> <ul style="list-style-type: none"> <li data-bbox="842 857 1913 1219">U.S. Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
19(h)	[the microfluidic device comprises] a second valve disposed downstream of the DNA manipulation zone;	<p data-bbox="793 1263 1808 1328">The accused system comprises a microfluidic device comprising a second valve disposed downstream of the DNA manipulation zone</p> <p data-bbox="793 1365 1850 1398"><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6,</p>

Claim	Claim Language	Infringement Evidence
		<p>2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08  <p>The diagram consists of four panels labeled A, B, C, and D, illustrating the operation of a microfluidic cartridge. Panel A shows a pipette tip dispensing a droplet into a channel. Panel B shows the droplet moving through a channel. Panel C shows the droplet entering a chamber. Panel D shows the droplet entering a chamber. Below these panels is a larger diagram showing a 'Second valve' and a 'PCR' chamber. The 'Second valve' is indicated by a red arrow pointing to a red oval. The 'PCR' chamber is indicated by a red arrow pointing to a green oval containing three green droplets.</p>

Claim	Claim Language	Infringement Evidence
		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second

Claim	Claim Language	Infringement Evidence
		<p>branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1297 488 1430 521">FIG. 1J</p> <p data-bbox="1297 789 1430 821">FIG. 1K</p> <p data-bbox="1541 789 1709 821">○ OCCLUDED</p> <ul data-bbox="842 854 1921 1211" style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
19(i)	a controller programmed to close the first and second valves to prevent gas and liquid from	The accused system comprises a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone and to isolate and confine the sample to a region between the first and second valves

Claim	Claim Language	Infringement Evidence
	flowing into or out of the DNA manipulation zone and to isolate and confine the sample to a region between the first and second valves accessible to the detector,	<p>accessible to the detector.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.”

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 24, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway;

Claim	Claim Language	Infringement Evidence
		<p>capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads.</p> <ul style="list-style-type: none"> • Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber. • U.S. Patent No. 9,339,812 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)

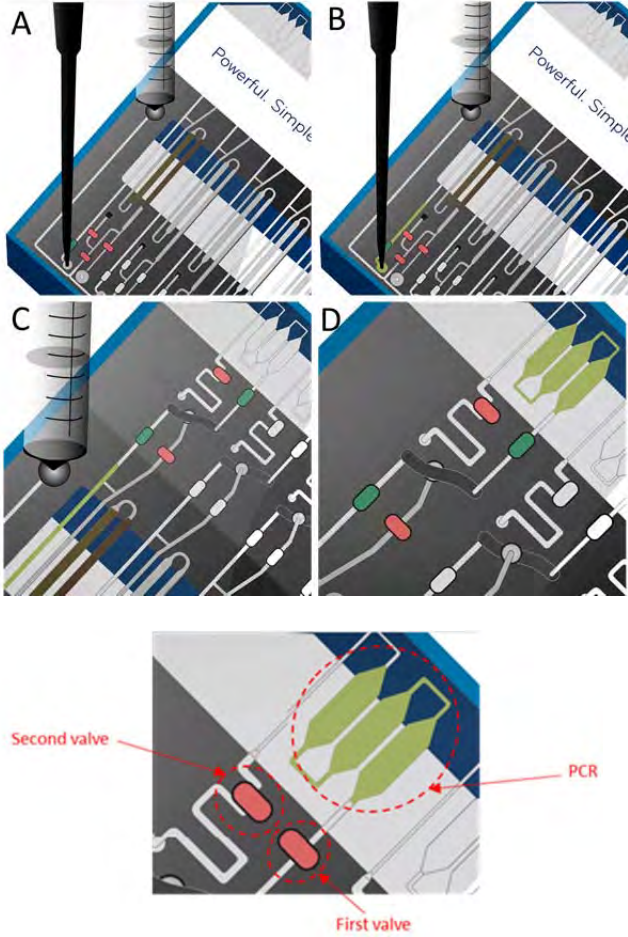
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • U.S. Patent No. 9,339,812 at 3:41-46 (“The detection chamber heaters 157, optical subsystem 180 and valve actuation subsystem 170 of the molecular diagnostic module 130 then facilitate analysis of the set of nucleic acid-reagent mixtures by a processor configured to display information on a user interface.”) • U.S. Patent No. 9,339,812 at 26:25-32 (“In a variation wherein the controller 272 is coupled to the molecular diagnostic module 130, the controller 272 preferably functions to automate reception of a microfluidic cartridge, heating of biological samples within the molecular diagnostic module 130 and the detection chambers 213, occlusion of fluidic pathways 220 by the valve actuation subsystem 170, and analysis of a set of nucleic acid-reagent mixtures by the optical subsystem 180.”) • U.S. Patent No. 9,339,812 at 33:3-39 (“Embodiments of the method 400 and variations thereof can be embodied and/or implemented at least in part by a machine configured to receive a computer-readable medium storing computer-readable instructions. The instructions are preferably executed by computer-executable components preferably integrated with the system 100 and one or more portions of the processor 273 and/or the controller 272. The computer-readable medium can be stored on any suitable computer-readable media such as RAMs, ROMs, flash memory, EEPROMs, optical devices (CD or DVD), hard drives, floppy drives, or any suitable device. The computer-executable component is preferably a general or application specific processor, but any suitable dedicated hardware or hardware/firmware combination device can alternatively or additionally execute the instructions. The FIGURES illustrate the architecture, functionality and operation of possible implementations of systems, methods and computer program products according to preferred embodiments, example configurations, and variations thereof. In this regard, each block in the flowchart or block diagrams may represent a module, segment, or portion of code, which comprises one or more executable instructions for implementing the specified logical function(s). It should also be noted that, in some alternative implementations, the functions noted in the block can occur out of the order noted in the FIGURES. For example, two blocks

Claim	Claim Language	Infringement Evidence
		<p>shown in succession may, in fact, be executed substantially concurrently, or the blocks may sometimes be executed in the reverse order, depending upon the functionality involved. It will also be noted that each block of the block diagrams and/or flowchart illustration, and combinations of blocks in the block diagrams and/or flowchart illustration, can be implemented by special purpose hardware-based systems that perform the specified functions or acts, or combinations of special purpose hardware and computer instructions.”)</p> <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined

Claim	Claim Language	Infringement Evidence
		<p>between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> • US Patent No. 9,738,887 at 12:11-19 (“When not in operation, however, the normally closed position 43 is configured to prevent leakage and/or fluid bypass. The normally closed position may also be held closed by an occluding object, to prevent leakage even under pressure provided by a fluid delivery system, or under pressure experienced during a high temperature step (e.g., thermocycling) to prevent evaporation of a sample undergoing thermocycling.”) • US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by

Claim	Claim Language	Infringement Evidence
		<p>using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at Figs. 1J and 1K: <div data-bbox="961 646 1745 927" data-label="Diagram"> </div> <div data-bbox="1297 889 1430 927">FIG. 1J</div> <div data-bbox="961 946 1745 1227" data-label="Diagram"> </div> <div data-bbox="1297 1190 1430 1227">FIG. 1K</div> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection

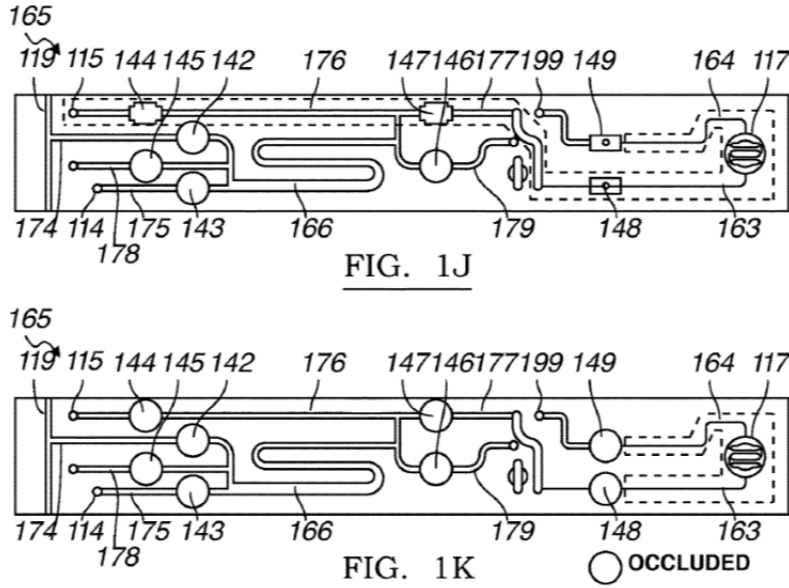
Claim	Claim Language	Infringement Evidence
		chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
19(j)	wherein the only ingress to and egress from the region accessible to the detector is through the first and second valves; and	<p>In the accused system, the only ingress to and egress from the region accessible to the detector is through the first and second valves.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

Claim	Claim Language	Infringement Evidence
		 <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module,

Claim	Claim Language	Infringement Evidence
		<p>the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads.</p> <ul style="list-style-type: none"> • Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber. <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve

Claim	Claim Language	Infringement Evidence
		<p>guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
19(k)	wherein the computer-controlled heat source is in thermal contact with the DNA manipulation zone and	<p>The accused system comprises a computer-controlled heat source in thermal contact with the DNA manipulation zone.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/,</p>

Claim	Claim Language	Infringement Evidence
		<p>last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO </p>

Claim	Claim Language	Infringement Evidence
		<p>NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, last visited May 31, 2019, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> • “There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.” • “The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate

Claim	Claim Language	Infringement Evidence
		<p>connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled

Claim	Claim Language	Infringement Evidence
		<p>to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,499,896 at 2:21-32 (“As shown in FIGS. 1A and 1B, an embodiment of a system 100 for thermocycling biological samples within detection chambers comprises: a set of heater-sensor dies 110; an electronics substrate 140 that couple the set of heater-sensor dies to a controller; a set of heat sink supports 150 coupled to at least one of the electronics substrate and the set of heater-sensor dies; and a set of elastic elements 160 coupled to the electronics substrate and configured to bias each of the set of heater-sensor dies against a detection 30 chamber. In some embodiments, the system 100 further comprises a controller 165 and/or a cooling subsystem 170 configured to actively cool the system 100.”) • U.S. Patent No. 9,499,896 at 9:11-19 (“As shown in FIGS. 1, 4A-4B, and 7A-7C, the system 100 can further comprise an electronics substrate 140 configured to couple heating and sensing elements of the set of heater-sensor dies to a controller 165, a set of heat-sink supports 150 configured to facilitate heat dissipation within the system 100, a set of elastic elements 160 configured to bias the set of heater-sensor dies 110 against detection chambers for sample processing, and can additionally comprise the controller 165 and/or a cooling subsystem 170.”) • U.S. Patent No. 9,499,896 at 12:20-31 (“In a specific example, the controller 165 comprises a Yokogawa UT750 PID controller, an Arduino UNO R3 microcontroller configured to cycle the UT750 through temperature stages and to control temperature holding, a resistance-to-voltage conversion circuit, and two power supplies—a first power supply configured to supply power to the set of heater-sensor dies 110 and a second power supply configured to supply voltage to the resistance-to-voltage conversion circuit. In the specific example, the controller 165 comprises a resistance-to-voltage

Claim	Claim Language	Infringement Evidence
		<p>conversion circuit because the UT750 PID controller requires voltage as an input for PID control.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 11:63-12:4 “As shown in FIGS. 1A and 1B, the system 100 can further comprise a controller 165, which functions to automate and/or control heating parameters provided by the set of heater-sensor dies 110. The controller 165 can further be configured to provide heat parameter output commands to the heating element(s) 114, and/or configured to receive communication of heating parameters (e.g., detected temperatures) sensed at the sensing element(s) 115 of the system 100.”
19(l)	wherein the detector is configured to identify one or more polynucleotides within the DNA manipulation zone.	<p>The accused system comprises a detector configured to identify one or more polynucleotides within the DNA manipulation zone.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/product/neumodx-288/, last visited June 3, 2019 (Exhibit 13)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/product/neumodx-96/, last visited June 3, 2019 (Exhibit 14)</p> <ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p>JFO_2018-10-25_8009-Rev-B_NeuMoDx-96-Spec-Sheet (Exhibit 21)</p>

Claim	Claim Language	Infringement Evidence																																				
		<table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>NeuMoDx_288_Spec_Sheet_R2.pdf (Exhibit 22)</p> <table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>US10041062 (Exhibit 33)</p> <ul style="list-style-type: none"> Claim 1. A molecular diagnostic system configured to process a biological sample within a cartridge and separate a nucleic acid volume from the biological sample, the molecular diagnostic system comprising: a cartridge platform that supports the cartridge and comprising a magnet receiving slot configured to be aligned with the cartridge in a first operation mode; a nozzle of a liquid handling subsystem; an optical subsystem; a cartridge heater; a magnet vertically aligned with the magnet receiving slot; and an actuator coupled to the nozzle of the liquid handling subsystem, the optical subsystem, and the cartridge heater, the actuator configured to vertically displace the cartridge platform in the first operation mode to a position wherein: the nozzle of the liquid handling system is coupled to a fluid port of the cartridge, wherein the fluid port of the cartridge receives fluids for processing the biological sample, the magnet passes through the magnet receiving slot of the cartridge platform and interfaces with a first portion of the cartridge, the optical subsystem interfaces with a second portion 	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass
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Claim	Claim Language	Infringement Evidence
		<p>of the cartridge, wherein the second portion of the cartridge receives a processed derivative of the nucleic acid volume, and a third region of the cartridge is compressed between the cartridge heater and the cartridge platform.</p> <ul style="list-style-type: none"> • Claim 8. The system of claim 1, wherein the optical subsystem comprises at least one unit including an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the biological sample, and to transmit emitted light from the biological sample, through the emission filter, and toward the photodetector. <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater. • Claim 11. The system of claim 1, wherein the molecular diagnostic module further comprises an optical subsystem comprising a first unit and a second unit, wherein each of the first unit and the second unit includes a set of excitation filters, a set of emission filters, a set of photodetectors aligned

Claim	Claim Language	Infringement Evidence
		<p>with the set of emission filters, and a set of dichroic mirrors configured to reflect light from the set of excitation filters toward one of a set of nucleic acid-reagent mixtures at the cartridge, and to transmit emitted light from one of the set of nucleic acid-reagent mixtures, through at least one of the set of emission filters, and toward at least one of the set of photodetectors.</p> <ul style="list-style-type: none"> • Claim 12. The system of claim 11, wherein the molecular diagnostic module further includes a set of detection chamber heaters configured to heat a set of detection chambers through the second surface of the cartridge, and wherein the optical subsystem is configured to receive light, emitted from the set of nucleic acid-reagent mixtures at the set of detection chambers, from the first surface of the cartridge.

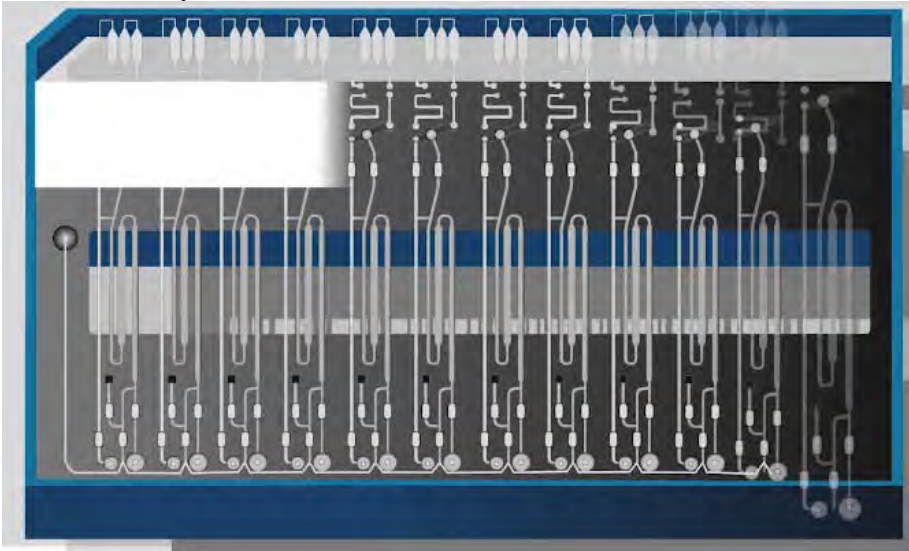
Exhibit 35

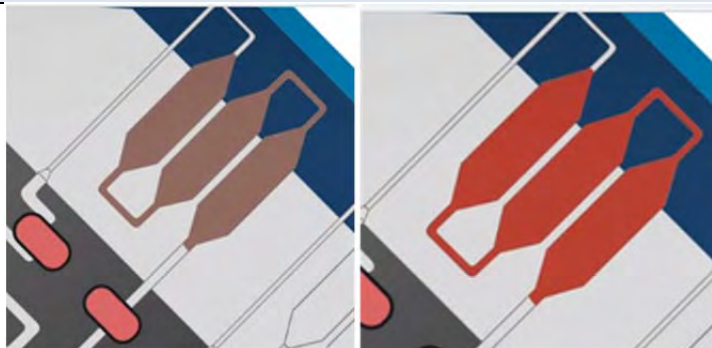
U.S. Patent No. 8,703,069 Infringement Chart

Claim	Claim Language	Infringement Evidence
1(a)	1. A method of amplifying a nucleic acid-containing sample within a microfluidic device, the method comprising:	<p>To the extent the preamble is limiting, the accused workflow is a method of amplifying a nucleic acid-containing sample within a microfluidic device.</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.” <div data-bbox="884 553 1635 1024" data-label="Image"> </div> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.”

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/product/neumodx-288/, last visited June 3, 2019 (Exhibit 13)</p> <ul style="list-style-type: none"> • “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/product/neumodx-96/, last visited June 3, 2019 (Exhibit 14)</p> <ul style="list-style-type: none"> • “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of

Claim	Claim Language	Infringement Evidence
		<p>products of amplification.”</p> <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>0600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> “NeuMoDx™ RELEASE Solution INSTRUCTIONS FOR USE... The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) and the dried Master Mix contained in a NeuMoDx test strip. The System then dispenses the prepared RT-PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.” <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

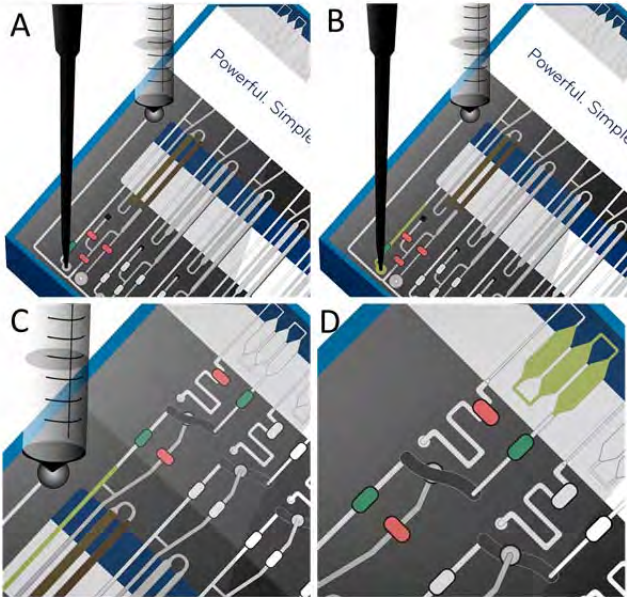
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> <li data-bbox="846 238 1898 342">• “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> <li data-bbox="846 899 1856 1003">• “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 <li data-bbox="846 1013 1923 1224">• “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

Claim	Claim Language	Infringement Evidence										
		<div></div> <p>“Patents”, http://www.neumodx.com/patents/, demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 9,539,576; 9,637,775; and 10,093,963. (Exhibit 15)</p> <h2>PATENTS</h2> <table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.</td></tr></table> <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none">Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636.	XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.
Product	Patents											
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Claim	Claim Language	Infringement Evidence
		<p>substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent port, the fluid port, and the detection chamber.</p> <ul style="list-style-type: none"> • Claim 11. The cartridge of claim 1, wherein the detection chamber comprises a first, a second, and a third detection chamber segment wherein each of the first, the second, and the third detection chamber segment is a broad chamber of which a projection onto a plane is substantially rectangular, wherein a first end of the second detection chamber segment is connected to the first detection chamber segment by a first narrow fluidic channel, and wherein a second end of the second detection chamber segment is connected to the third detection chamber segment by a second narrow fluidic channel. • U.S. Patent No. 9,738,887 at FIG. 1A:

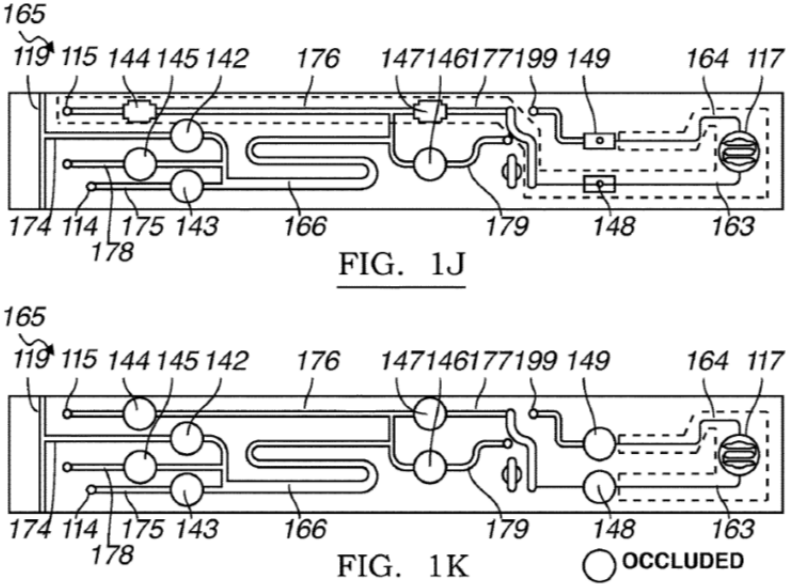
Claim	Claim Language	Infringement Evidence
		<div data-bbox="892 228 1669 755"> </div> <p data-bbox="1213 755 1346 792"><u>FIG. 1A</u></p> <ul style="list-style-type: none"> <p data-bbox="842 846 1921 1317">U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region.”)</p> <p data-bbox="842 1325 1921 1427">US Patent No. 9,738,887 at 2:36-3:5. (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-</p>

Claim	Claim Language	Infringement Evidence
		<p>reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140... In a specific application, the microfluidic cartridge 100 can be used to facilitate a PCR procedure for analysis of a sample containing nucleic acids.")</p> <ul style="list-style-type: none"> • US Patent No. 9,738,887 at 13:7-18. ("The top layer 110 of an embodiment of the microfluidic cartridge 100 functions to accommodate elements involved in performing a molecular diagnostic procedure (e.g. PCR), such that a sample containing nucleic acids, passing through the cartridge, can be manipulated by the elements involved in performing the molecular diagnostic procedure. The top layer 110 is preferably composed of a structurally rigid/stiff material with low autofluorescence, such that the top layer 110 does not interfere with sample detection by fluorescence or chemiluminescence techniques, and an appropriate glass transition temperature and chemical compatibility for PCR or other amplification techniques.") • US Patent No. 9,738,887 at 13:35-42. ("The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.") • US Patent No. 9,738,887 at 15:29-39 ("The segments may be arranged in at least one of several configurations to facilitate isolation, processing, and amplification of a nucleic acid sample ..."). • US Patent No. 9,738,887 at 23:20-24 ("The top layer 110 of the specific embodiment of the microfluidic cartridge 100 functions preferably as described

Claim	Claim Language	Infringement Evidence
		in Section 1.1, and is composed of polypropylene with low autofluorescence and a glass transition temperature suitable for PCR. ")
1(b)	moving the sample from an upstream channel of the microfluidic device into a DNA manipulation module located downstream of the upstream channel,	<p>The accused workflow includes moving the sample from an upstream channel of the microfluidic device into a DNA manipulation module located downstream of the upstream channel.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMoDx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

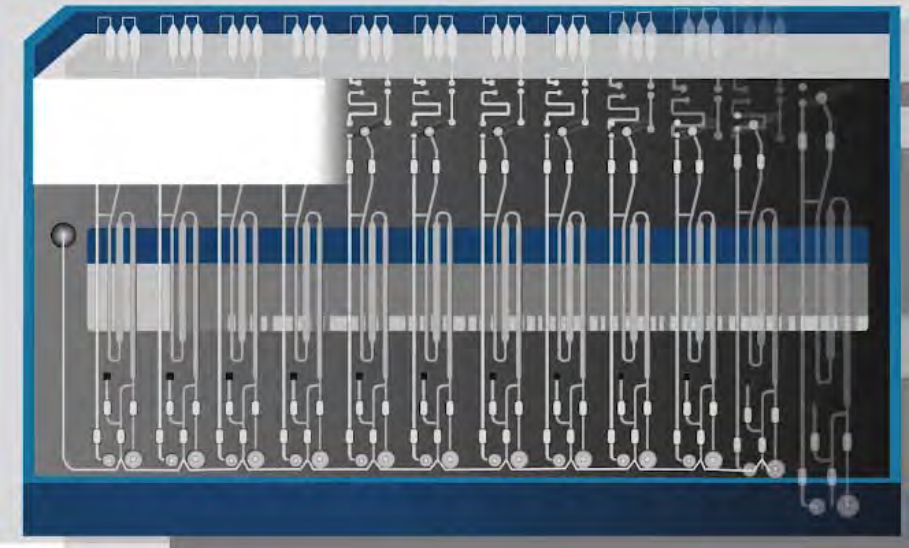
Claim	Claim Language	Infringement Evidence
		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion

Claim	Claim Language	Infringement Evidence
		<p>positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> • US Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) • US Patent No. 9,738,887 at 15:31-35 (“The segment running to a detection chamber 163 functions to deliver a processed sample fluid to the detection chamber 117 with a reduced quantity of gas bubbles, and the segment running away from the detection chamber 164 functions to deliver a fluid away from the detection chamber 117.”) • US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid

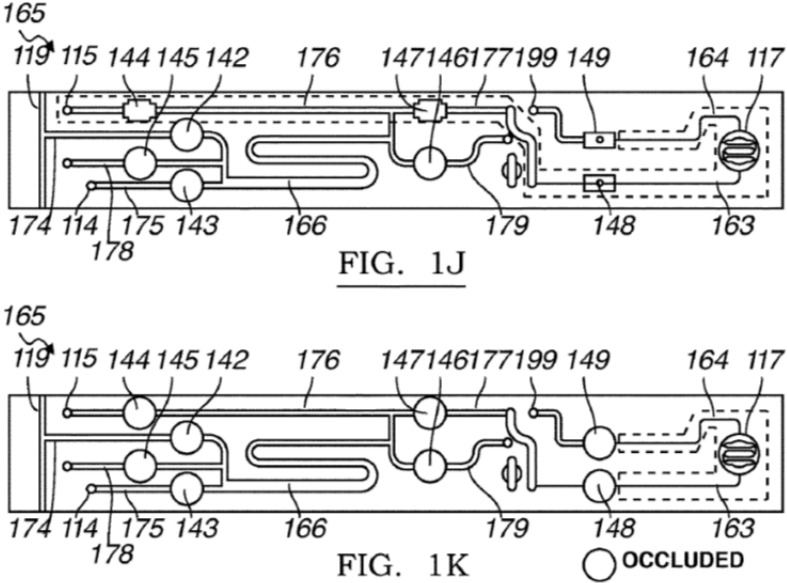
Claim	Claim Language	Infringement Evidence
		<p>sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at Figs. 1J and 1K:  <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p>
1(c)	the DNA manipulation module including a DNA manipulation zone configured to perform amplification of the sample,	<p>The accused workflow includes a DNA manipulation module including a DNA manipulation zone configured to perform amplification of the sample.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

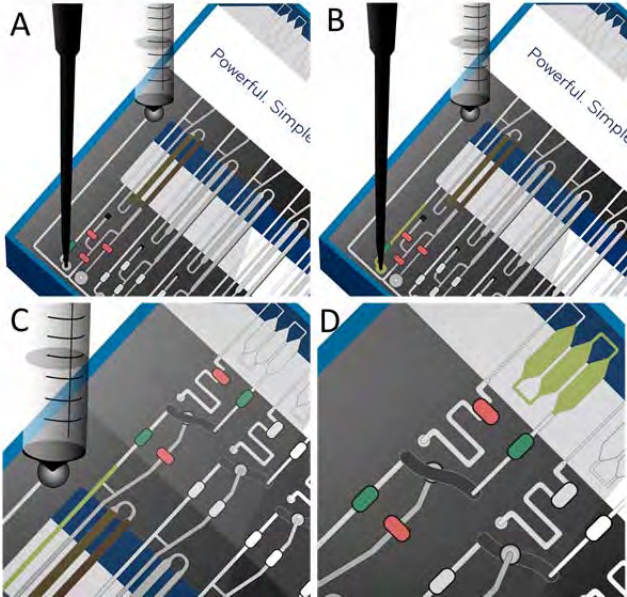
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 <div data-bbox="905 354 1528 948"> </div> <p> <i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10) </p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p> <i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 24, 2019 (Exhibit 11) </p> <ul style="list-style-type: none"> “The NeuMoDx™ Molecular Systems are a family of scalable platforms that

Claim	Claim Language	Infringement Evidence
		<p>fully integrate the entire molecular diagnostic process from ‘sample to result’. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.”</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>0600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> • “NeuMoDx™ RELEASE Solution INSTRUCTIONS FOR USE... The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) and the dried Master Mix contained in a NeuMoDx test strip. The System then dispenses the prepared RT-PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.”

Claim	Claim Language	Infringement Evidence
		<p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.”

Claim	Claim Language	Infringement Evidence
		<p><i>Id.</i> at 3:58-4:08</p> <p>U.S. Patent No. 9,738,887</p> <ul style="list-style-type: none"> Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent port, the fluid port, and the detection chamber. U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste chamber, and to pass through the vent region”) U.S. Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which

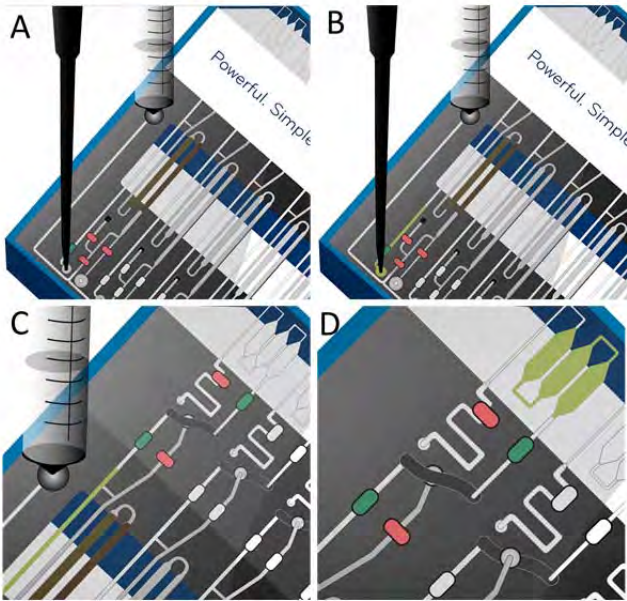
Claim	Claim Language	Infringement Evidence
		<p>volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.")</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 17:27-49 ("Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115.... An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.") U.S. Patent No. 9,738,887 at Figs. 1J and 1K:  <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p>

Claim	Claim Language	Infringement Evidence
1(d)	a first valve disposed upstream of the DNA manipulation zone,	<p>The accused workflow includes a first valve disposed upstream of the DNA manipulation zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. <u>(Exhibit 16)</u></p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

Claim	Claim Language	Infringement Evidence
		<div data-bbox="1079 228 1528 532" data-label="Image"> </div> <p data-bbox="793 613 1115 646">US9738887 (Exhibit 31)</p> <ul data-bbox="842 654 1919 1414" style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second

Claim	Claim Language	Infringement Evidence
		<p>surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured

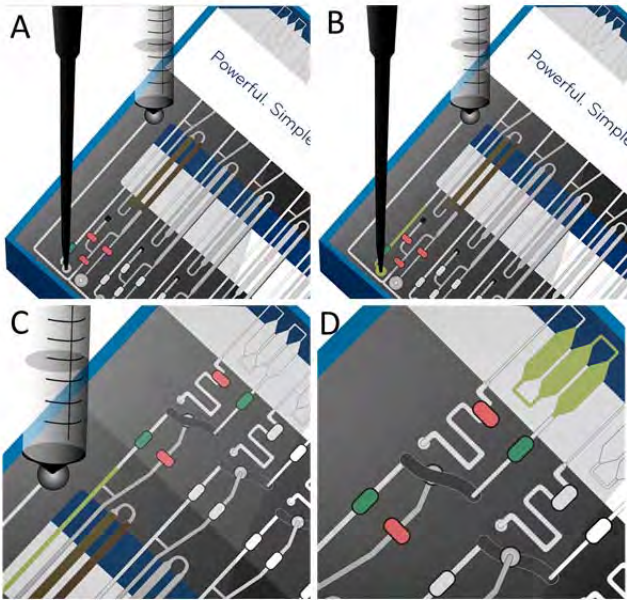
Claim	Claim Language	Infringement Evidence
		<p>to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)at Figs. 1J and 1K:</p> <div data-bbox="961 386 1745 646"> <p>FIG. 1J</p> </div> <div data-bbox="961 686 1745 963"> <p>FIG. 1K</p> <p>○ OCCLUDED</p> </div> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)

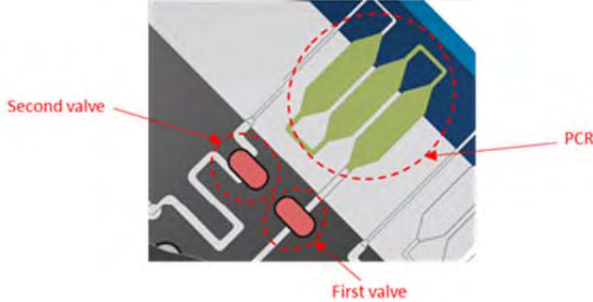
Claim	Claim Language	Infringement Evidence
1(e)	and a second valve disposed downstream of the DNA manipulation zone,	<p>The accused workflow includes a second valve disposed downstream of the DNA manipulation zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

Claim	Claim Language	Infringement Evidence
		<div data-bbox="940 228 1537 495" data-label="Image"> </div> <p data-bbox="793 532 1117 565">US9738887 (Exhibit 31)</p> <ul data-bbox="842 573 1915 1408" style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a

Claim	Claim Language	Infringement Evidence
		<p>closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic

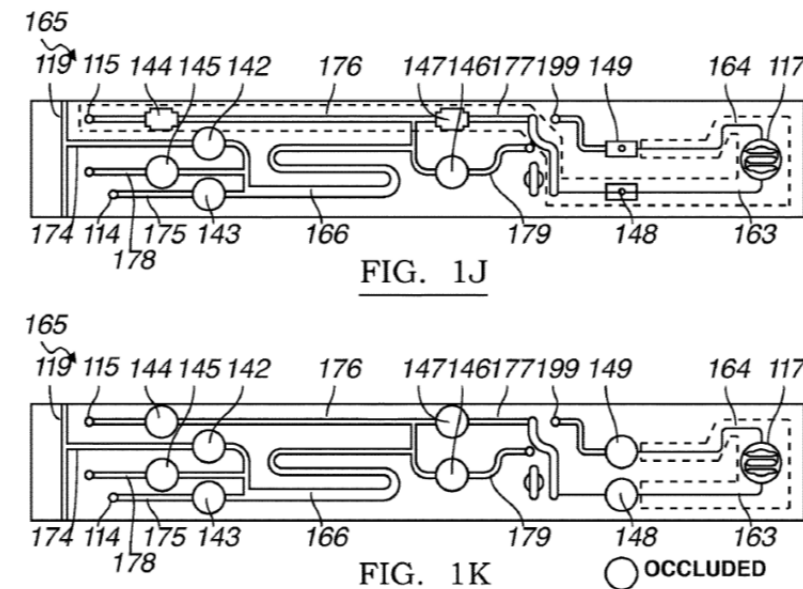
Claim	Claim Language	Infringement Evidence
		<p>system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)at Figs. 1J and 1K:</p> <div data-bbox="961 354 1745 613"> <p>FIG. 1J</p> </div> <div data-bbox="961 651 1745 938"> <p>FIG. 1K</p> <p>○ OCCLUDED</p> </div> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
1(f)	the only ingress to and egress	In the accused workflow, the only ingress to and egress from the DNA manipulation

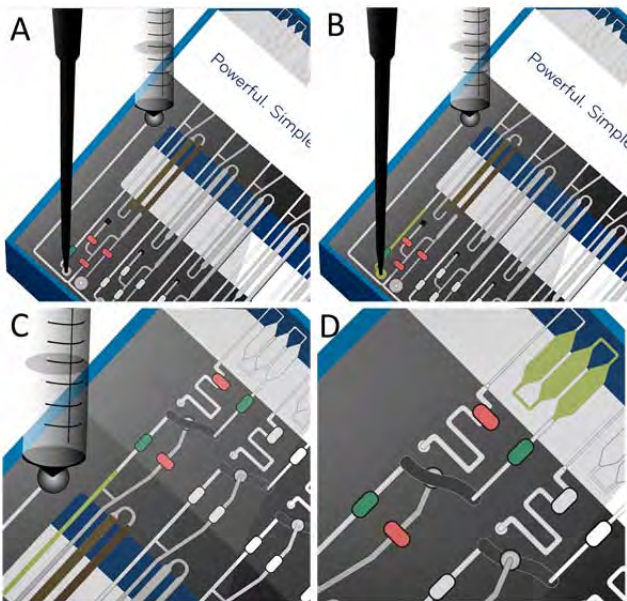
Claim	Claim Language	Infringement Evidence
	from the DNA manipulation zone being through the first valve and the second valve;	<p>zone being through the first valve and the second valve.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

Claim	Claim Language	Infringement Evidence
		 <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads. • Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to

Claim	Claim Language	Infringement Evidence
		<p>facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber.</p> <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second

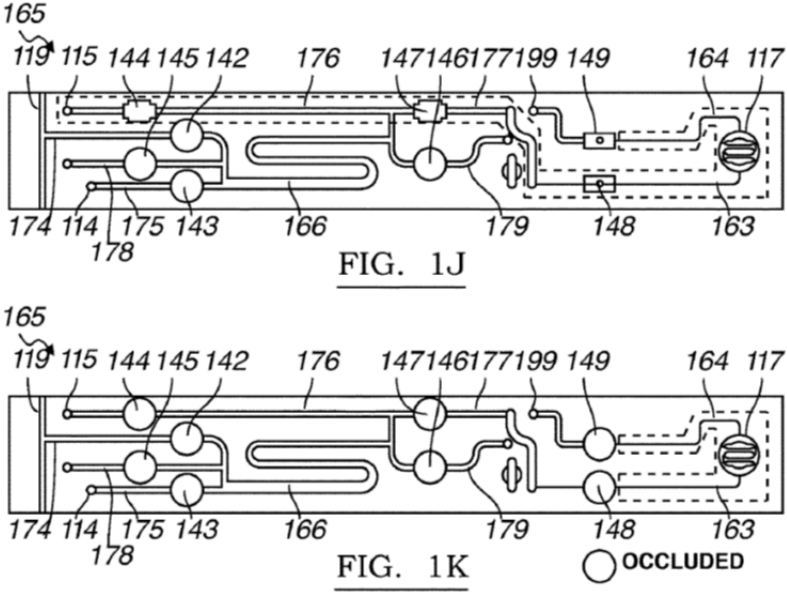
Claim	Claim Language	Infringement Evidence
		<p>surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144,

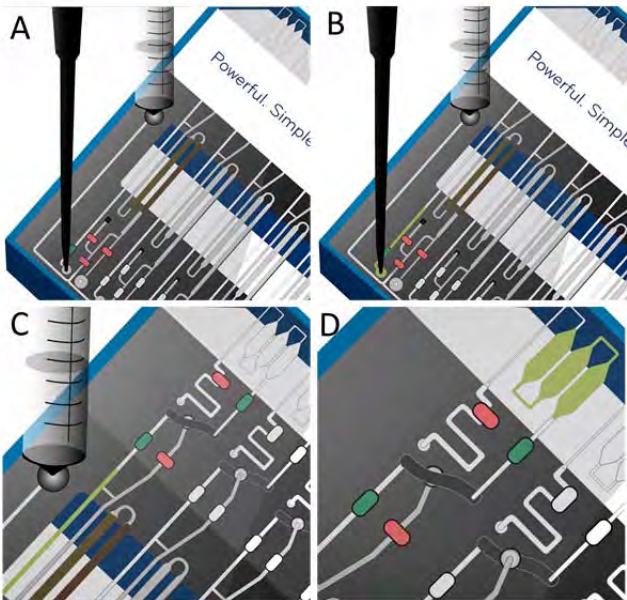
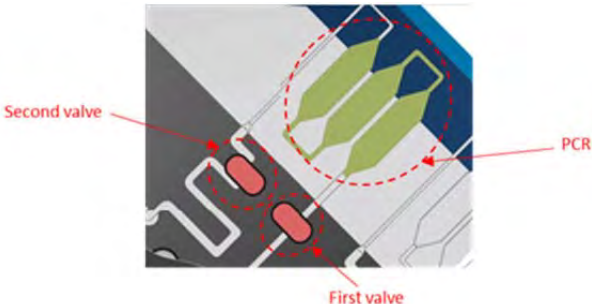
Claim	Claim Language	Infringement Evidence
		<p>147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)at Figs. 1J and 1K:</p>  <p>FIG. 1J</p> <p>FIG. 1K</p> <p>O CCLUDED</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as

Claim	Claim Language	Infringement Evidence
		shown in FIG. 1C.”)
1(g)	receiving the sample in the DNA manipulation zone;	<p>The accused workflow includes receiving the sample in the DNA manipulation zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08  <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection

Claim	Claim Language	Infringement Evidence
		<p>chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p>

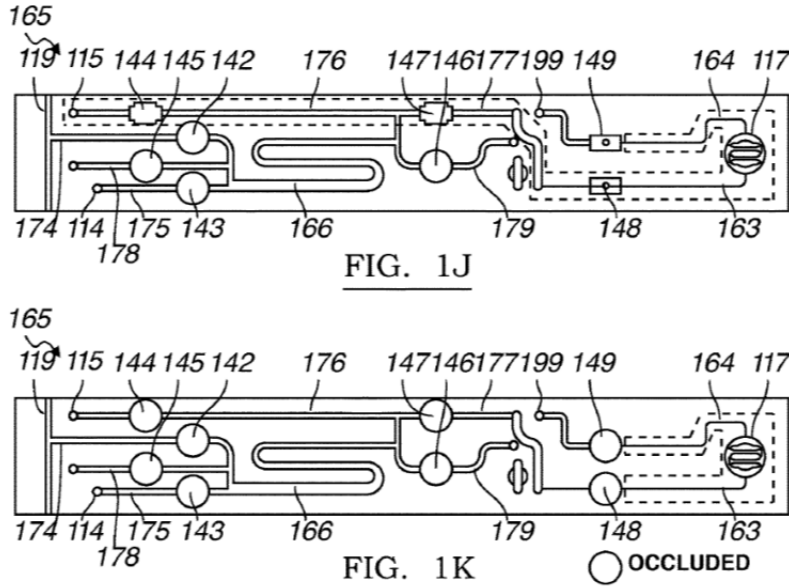
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • US Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) • US Patent No. 9,738,887 at 15:31-35 (“The segment running to a detection chamber 163 functions to deliver a processed sample fluid to the detection chamber 117 with a reduced quantity of gas bubbles, and the segment running away from the detection chamber 164 functions to deliver a fluid away from the detection chamber 117.”) • US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic

Claim	Claim Language	Infringement Evidence
		<p>pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at Figs. 1J and 1K:  <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p>
1(h)	closing the first valve and the second valve such that gas and liquid are prevented from flowing into or out of the DNA manipulation zone; and	<p>The accused workflow includes closing the first valve and the second valve such that gas and liquid are prevented from flowing into or out of the DNA manipulation zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process

Claim	Claim Language	Infringement Evidence
		<p data-bbox="890 233 1205 266">begins.” <i>Id.</i> at 3:58-4:08</p>   <p data-bbox="793 1289 1115 1321">US9738887 (Exhibit 31)</p> <ul data-bbox="842 1328 1898 1398" style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection

Claim	Claim Language	Infringement Evidence
		<p>chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> US Patent No. 9,738,887 at 12:11-19 (“When not in operation, however, the normally closed position 43 is configured to prevent leakage and/or fluid bypass. The normally closed position may also be held closed by an occluding object, to prevent leakage even under pressure provided by a fluid delivery system, or under pressure experienced during a high temperature step (e.g., thermocycling) to prevent evaporation of a sample undergoing thermocycling.”) US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) US Patent No. 9,738,887 at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
1(i)	thermal cycling the sample in the DNA manipulation zone.	<p>The accused workflow includes thermal cycling the sample in the DNA manipulation zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6,</p>

Claim	Claim Language	Infringement Evidence
		<p>2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 • “During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26 <div data-bbox="905 634 1612 980" data-label="Image"> </div> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 24, 2019 (Exhibit 11)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>0600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> “NeuMoDx™ RELEASE Solution INSTRUCTIONS FOR USE... The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) and the dried Master Mix contained in a NeuMoDx test strip. The System then dispenses the prepared RT-PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.” <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> A system for thermocycling biological samples within detection chambers


Claim	Claim Language	Infringement Evidence
		<p>comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <p>US9101930 (Exhibit 25)</p> <ul style="list-style-type: none"> Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the intermediate substrate by

Claim	Claim Language	Infringement Evidence
		<p>an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> • Claim 11. The cartridge of claim 10, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, wherein the first fluidic pathway is substantially identical to the second fluidic pathway, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. • Claim 22. The cartridge of claim 11, wherein at least one of the first detection chamber and the second detection chamber is configured to be optimized for volumetric capacity, thermocycling rates, optical detection, and filling in a manner that limits bubble generation. <p>US9604213 (Exhibit 30)</p> <ul style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids in cooperation with a cartridge comprising a heating region defined at a first surface, and a magnet housing region defined at a second surface in thermal communication with the first surface, the system comprising: a capture plate configured to facilitate combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate and separate nucleic acids from the set of magnetic beads, comprising: a cartridge platform configured to receive the cartridge and comprising a magnet receiving slot aligned with the second surface during operation, a heater configured to transmit heat to the heating region at the first surface during operation, and a magnet coupled to a magnet heating element that heats the magnet during operation with the magnet proximal the second surface, the magnet configured to pass through the magnet receiving slot into the magnet housing region during

Claim	Claim Language	Infringement Evidence
		<p>operation, thereby facilitating separation of a nucleic acid volume from the magnetic bead-sample and heating of the magnetic bead-sample in cooperation with the heater.</p> <ul style="list-style-type: none"> • Claim 11. The system of claim 1, wherein the molecular diagnostic module further comprises an optical subsystem comprising a first unit and a second unit, wherein each of the first unit and the second unit includes a set of excitation filters, a set of emission filters, a set of photodetectors aligned with the set of emission filters, and a set of dichroic mirrors configured to reflect light from the set of excitation filters toward one of a set of nucleic acid-reagent mixtures at the cartridge, and to transmit emitted light from one of the set of nucleic acid-reagent mixtures, through at least one of the set of emission filters, and toward at least one of the set of photodetectors. • Claim 12. The system of claim 11, wherein the molecular diagnostic module further includes a set of detection chamber heaters configured to heat a set of detection chambers through the second surface of the cartridge, and wherein the optical subsystem is configured to receive light, emitted from the set of nucleic acid-reagent mixtures at the set of detection chambers, from the first surface of the cartridge.


EXHIBIT 36

U.S. Patent No. 7,998,708 Infringement Chart

Claim	Claim Language	Infringement Evidence
1(a)	An apparatus, comprising:	<p>To the extent the preamble is limiting, the accused instruments are an apparatus.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p>  <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited</p>

Claim	Claim Language	Infringement Evidence
		<p>May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of

Claim	Claim Language	Infringement Evidence
		<p>the instrument with touchscreen computer, accessories, and reagents and consumables.”</p> <p><i>NeuMoDxTM Molecular Systems</i>, NEUMODx, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”)
1(b)	a multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone;	<p>The accused system comprises a multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone.</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

Claim	Claim Language	Infringement Evidence
		 <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized

Claim	Claim Language	Infringement Evidence
		<p>reagents.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59 <div data-bbox="890 342 1793 889" data-label="Image"> </div> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 <p> “Patents”, http://www.neumodx.com/patents/, demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 9,539,576; 9,637,775; and 10,093,963 (Exhibit 15) </p>

Claim	Claim Language	Infringement Evidence										
		<div><div>PATENTS</div><table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.</td></tr></table></div> <div>US9403165 (Exhibit 27)<ul style="list-style-type: none">Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic</div>	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636.	XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.
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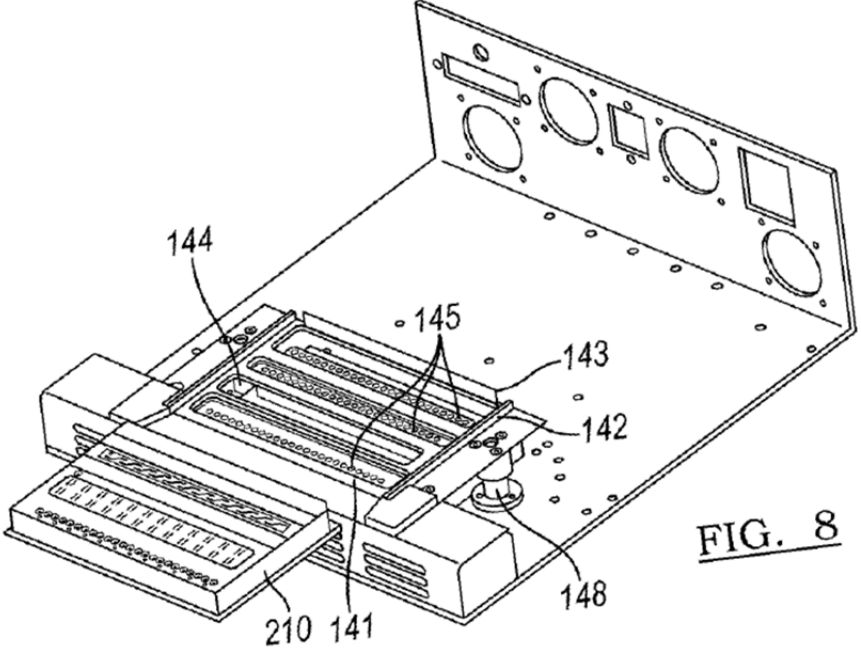
Claim	Claim Language	Infringement Evidence
		<p>pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to

Claim	Claim Language	Infringement Evidence
		<p>produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a

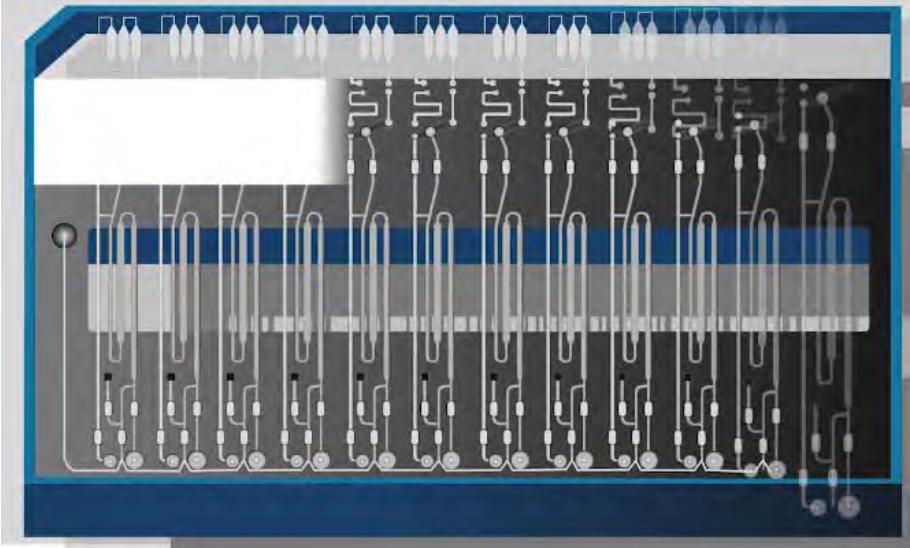
Claim	Claim Language	Infringement Evidence
		<p>capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent

Claim	Claim Language	Infringement Evidence
		<p>mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)</p>
1(c)	a receiving bay configured to receive the microfluidic cartridge;	<p>The accused system comprises a receiving bay configured to receive the microfluidic cartridge.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • at 4:55-5:00

Claim	Claim Language	Infringement Evidence
		  <p data-bbox="793 1122 1115 1159">US9050594 (Exhibit 24)</p> <ul data-bbox="842 1166 1921 1414" style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator

Claim	Claim Language	Infringement Evidence
		<p>configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 2:6-7 (“FIG. 8 depicts an embodiment of a microfluidic cartridge and an embodiment of a cartridge platform.”) • U.S. Patent No. 9,050,594 at Fig. 8  <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 7:53-8:35 “As shown in FIG. 9A, the cartridge receiving module 140 of the molecular diagnostic module 130 comprises a cartridge platform 141 including a cartridge loading guiderail 142, a cartridge

Claim	Claim Language	Infringement Evidence
		<p>stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145; a linear actuator 146 configured to displace a microfluidic cartridge 210 resting on the cartridge platform 141, and a set of springs 148 coupled to the cartridge platform 141. The cartridge receiving module 140 thus functions to receive, align, and compress a microfluidic cartridge 210 for processing of a biological sample according to a molecular diagnostic assay protocol.... The cartridge platform 141 includes a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145, and functions to receive and align a microfluidic cartridge 210, while providing access to the microfluidic cartridge 210 by a magnet 160 and a valve actuation subsystem 170. As shown in FIG. 8, an embodiment of the cartridge platform 141 includes a pair of parallel cartridge loading guiderails 142, initiating at a pair of inwardly tapering protrusions configured to guide a microfluidic cartridge toward the pair of parallel cartridge loading guiderails 142, and spanning two short edges of the cartridge platform 141. The embodiment of the cartridge platform 141 also includes a cartridge stop 143 comprising a vertical tab oriented perpendicular to the cartridge loading guiderails 142, and spanning a long edge of the cartridge platform. Preferably, the cartridge loading guiderails 142 and the cartridge stop 143 are configured such that a microfluidic cartridge 210 slides between the cartridge loading guiderails 142 and hits the cartridge stop 143 to signal proper alignment.”</p>
1(d)	each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source maintains a substantially uniform temperature throughout the PCR reaction zone and thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing	<p>The accused system comprises a multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone and each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source maintains a substantially uniform temperature throughout the PCR reaction zone and thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936.</p>

Claim	Claim Language	Infringement Evidence
	sample in the PCR reaction zone;	<p>(Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 228 1612 574" data-label="Image"> </div> <p data-bbox="793 613 1877 683"><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="842 695 1919 1019" style="list-style-type: none"> • “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p data-bbox="793 1057 1115 1089">US9050594 (Exhibit 24)</p> <ul data-bbox="842 1101 1919 1421" style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet

Claim	Claim Language	Infringement Evidence
		<p>receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module

Claim	Claim Language	Infringement Evidence
		<p>comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic

Claim	Claim Language	Infringement Evidence
		<p>pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers. U.S. Patent No. 9,499,896 at 2:33-48 “The system 100 functions to enable

Claim	Claim Language	Infringement Evidence
		<p>rapid thermal cycling of samples while providing uniform heating and preventing signal drift. In specific applications, the system 100 can be used to rapidly and controllably thermocycle nucleic acid samples during performance of molecular diagnostic amplification techniques (e.g., PCR, RT-PCR), signal amplification techniques (e.g., bDNA, hybrid capture), and analytical techniques (e.g., gel electrophoresis, mass spectrometry). The system 100 can also provide rapid thermocycling without significant power requirements, ensure a closer correlation between the actual heating temperature and the temperature set-point by implementing an integrated heater-sensor die, and controllably and individually heat small sample volumes (e.g., picoliters, nanoliters) based upon a microfabrication technique that also enables mass production of the system 100.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,499,896 at 2:61-3:3 (“The set of heater-sensor dies 110 functions to controllably heat individual sample volumes. Preferably, each heater sensor die 111 is a thin-film die that can be deposited onto another substrate (e.g., silicon, glass substrate) that can be packaged onto an electronics substrate 140 (e.g., printed circuit board, PCB); however, each heater-sensor die 111 can alternatively comprise any suitable geometry and/or configuration that enables controlled, uniform, and rapid heating of a detection chamber in thermal communication with the heater-sensor die 111.”) • U.S. Patent No. 9,499,896 at 3:23-27 (“Preferably, each heater-sensor die 111 in the set of heater sensor dies 110 comprises an assembly including: a first insulating layer 112a that functions to provide an insulating barrier to isolate the heaters and sensors and a heating region 113 that functions to provide uniform sample heating.”) • U.S. Patent No. 9,499,896 at 12:15-20 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies 110.”)

Claim	Claim Language	Infringement Evidence
		<p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points. • U.S. Patent No. 9,539,576 at 9:8-12 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor

Claim	Claim Language	Infringement Evidence
		<p>dies 111 in the set of heater-sensor dies no.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,539,576 at 12:59-64 (“Upon completion of Block S240, individual heater-sensor dies of the set of heater-sensor dies can be coupled to one or multiple electronics substrates in order to provide uniform heating of individual sample containers with independent control of heating parameters provided at each of the set of heater-sensor dies.”)
1(e)	a detector configured to detect the presence of an amplification product in the respective PCR reaction zone; and	<p>The accused system comprises a detector configured to detect the presence of an amplification product in the respective PCR reaction zone.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by

Claim	Claim Language	Infringement Evidence																		
		<p>fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.”</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx™ Molecular Systems, NEUMODx,</i> http://www.neumodx.com/product/neumodx-288/, last visited June 3, 2019 (Exhibit 13)</p> <ul style="list-style-type: none"> • “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p><i>NeuMoDx™ Molecular Systems, NEUMODx,</i> http://www.neumodx.com/product/neumodx-96/, last visited June 3, 2019 (Exhibit 14)</p> <ul style="list-style-type: none"> • “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p>JFO_2018-10-25_8009-Rev-B_NeuMoDx-96-Spec-Sheet (Exhibit 21)</p> <table border="1"> <thead> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> </thead> <tbody> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </tbody> </table>	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass
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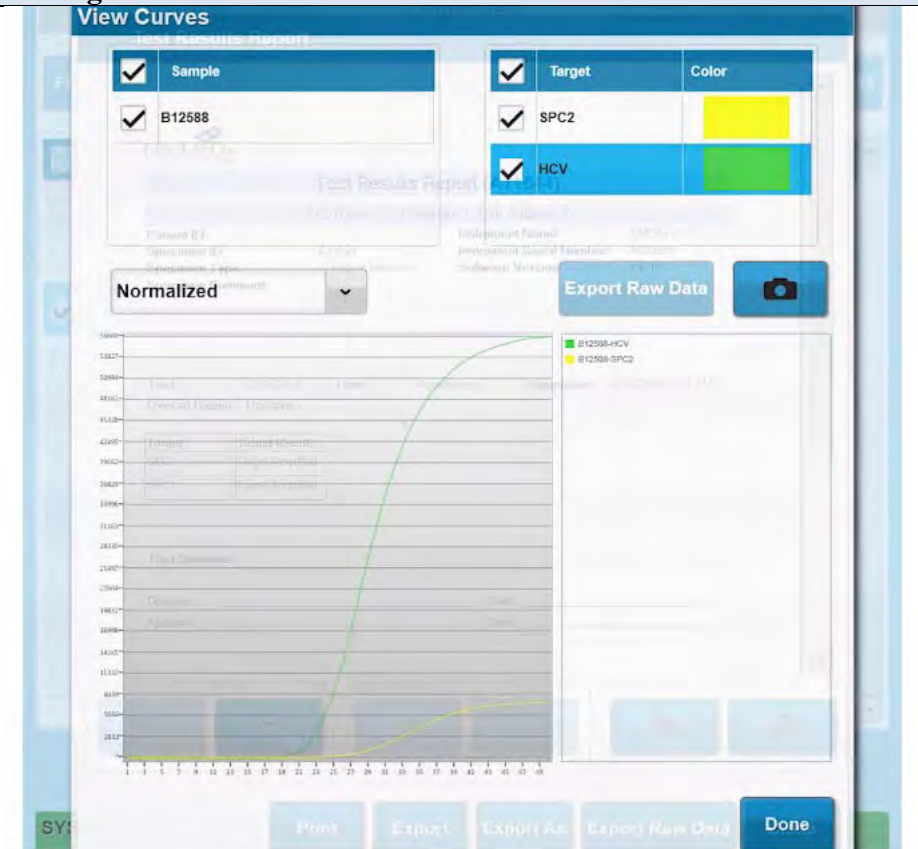
Claim	Claim Language	Infringement Evidence																		
		<p>NeuMoDx_288_Spec_Sheet_R2.pdf (Exhibit 22)</p> <table> <tr> <th>Optical Wavelengths</th><th>Excitation (nm)</th><th>Emission (nm)</th></tr> <tr> <td>1</td><td>470</td><td>510</td></tr> <tr> <td>2</td><td>530</td><td>555</td></tr> <tr> <td>3</td><td>585</td><td>610</td></tr> <tr> <td>4</td><td>625</td><td>660</td></tr> <tr> <td>5</td><td>680</td><td>715 long pass</td></tr> </table> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. 	Optical Wavelengths	Excitation (nm)	Emission (nm)	1	470	510	2	530	555	3	585	610	4	625	660	5	680	715 long pass
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Claim	Claim Language	Infringement Evidence
		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic

Claim	Claim Language	Infringement Evidence
		<p>acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12

Claim	Claim Language	Infringement Evidence
		<p>different pathways for sample processing.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)
1(f)	a processor coupled to the detector and the heat source, configured to control heating of one or more PCR reaction zones by the heat sources.	<p>The accused system comprises a processor coupled to the detector and the heat source, configured to control heating of one or more PCR reaction zones by the heat sources.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a


Claim	Claim Language	Infringement Evidence
		<p>platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

Claim	Claim Language	Infringement Evidence
		 <p><i>NeuMoDxTM Molecular Systems, NEUMODx, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</i></p> <ul style="list-style-type: none"> At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller”)

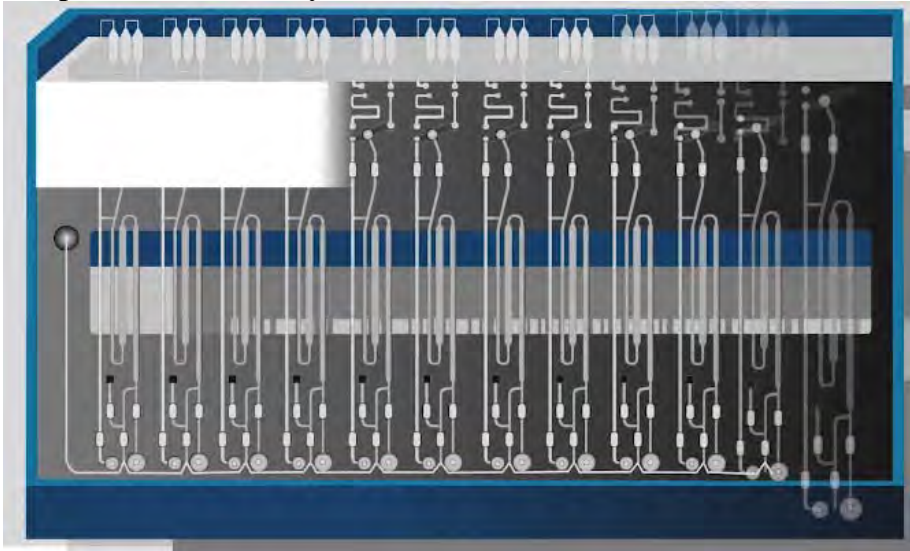
Claim	Claim Language	Infringement Evidence
		<p>footprint.”)</p> <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.

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		<p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers. • U.S. Patent No. 9,499,896 at 2:21-32 (“As shown in FIGS. 1A and 1B, an embodiment of a system 100 for thermocycling biological samples within detection chambers comprises: a set of heater-sensor dies 110; an electronics substrate 140 that couple the set of heater-sensor dies to a controller; a set of heat sink supports 150 coupled to at least one of the electronics substrate and the set of heater-sensor dies; and a set of elastic elements 160 coupled to the electronics substrate and configured to bias each of the set of heater-sensor dies against a detection 30 chamber. In some embodiments, the system 100 further comprises a controller 165 and/or a cooling subsystem 170 configured to actively cool the system 100.”) • U.S. Patent No. 9,499,896 at 9:11-19 (“As shown in FIGS. 1, 4A-4B, and 7A-

Claim	Claim Language	Infringement Evidence
		<p>7C, the system 100 can further comprise an electronics substrate 140 configured to couple heating and sensing elements of the set of heater-sensor dies to a controller 165, a set of heat-sink supports 150 configured to facilitate heat dissipation within the system 100, a set of elastic elements 160 configured to bias the set of heater-sensor dies 110 against detection chambers for sample processing, and can additionally comprise the controller 165 and/or a cooling subsystem 170.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 12:20-31 (“In a specific example, the controller 165 comprises a Yokogawa UT750 PID controller, an Arduino UNO R3 microcontroller configured to cycle the UT750 through temperature stages and to control temperature holding, a resistance-to-voltage conversion circuit, and two power supplies—a first power supply configured to supply power to the set of heater-sensor dies 110 and a second power supply configured to supply voltage to the resistance-to-voltage conversion circuit. In the specific example, the controller 165 comprises a resistance-to-voltage conversion circuit because the UT750 PID controller requires voltage as an input for PID control.”)U.S. Patent No. 9,499,896 at 11:63-12:4 “As shown in FIGS. 1A and 1B, the system 100 can further comprise a controller 165, which functions to automate and/or control heating parameters provided by the set of heater-sensor dies 110. The controller 165 can further be configured to provide heat parameter output commands to the heating element(s) 114, and/or configured to receive communication of heating parameters (e.g., detected temperatures) sensed at the sensing element(s) 115 of the system 100.”
33(a)	A method of carrying out PCR on a plurality of samples, the method comprising:	<p>To the extent the preamble is limiting, the accused workflow is a method of carrying out PCR on a plurality of samples.</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

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		 <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized

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		<p>reagents.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

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		<ul style="list-style-type: none"> <li data-bbox="846 235 1892 342">• “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> <li data-bbox="846 898 1892 1005">• “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 <p data-bbox="795 1044 1110 1076">US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> <li data-bbox="846 1084 1913 1406">• Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic


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		<p>pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste

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		<p>chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the

Claim	Claim Language	Infringement Evidence
		<p>dichroic mirror, and the emission filter.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12

Claim	Claim Language	Infringement Evidence
		<p>different pathways for sample processing.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)
33(b)	introducing the plurality of samples into a multi-lane microfluidic cartridge, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples;	<p>The accused workflow includes introducing the plurality of samples into a multi-lane microfluidic cartridge, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “The liquid handling robot aspirates the PCR-ready solution and transfers it back to the cartridge where it dispenses into the same P-port from which the sample was aspirated.” <i>Id.</i> at 3:47-3:57

Claim	Claim Language	Infringement Evidence
		

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 935 1115 967">US9101930 (Exhibit 25)</p> <ul data-bbox="842 976 1927 1408" style="list-style-type: none"> • Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the

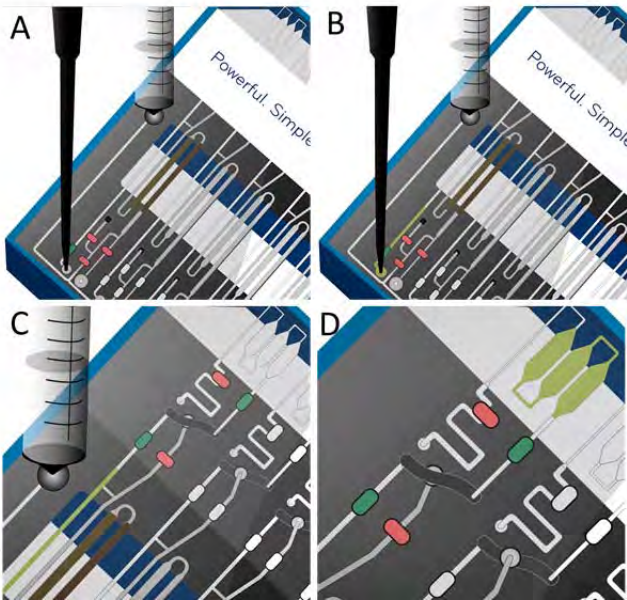
Claim	Claim Language	Infringement Evidence
		<p>intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> Claim 11. The cartridge of claim 10, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, wherein the first fluidic pathway is substantially identical to the second fluidic pathway, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second

Claim	Claim Language	Infringement Evidence
		<p>sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward

Claim	Claim Language	Infringement Evidence
		<p>the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) <p>U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to</p>

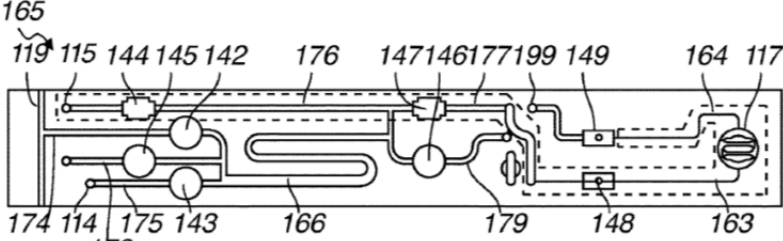
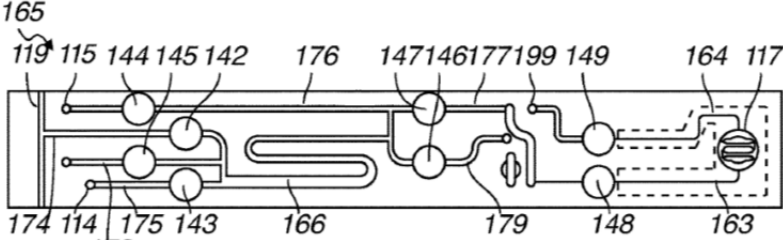
Claim	Claim Language	Infringement Evidence
		<p>the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers. U.S. Patent No. 9,499,896 at 12:15-20 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies 110.”) <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface


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		<p>with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,539,576 at 9:8-12 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies no.”) • U.S. Patent No. 9,539,576 at 12:59-64 (“Upon completion of Block S240, individual heater-sensor dies of the set of heater-sensor dies can be coupled to one or multiple electronics substrates in order to provide uniform heating of

Claim	Claim Language	Infringement Evidence
		individual sample containers with independent control of heating parameters provided at each of the set of heater-sensor dies.”)
33(c)	moving the plurality of samples into the respective plurality of PCR reaction zones; and	<p>The accused workflow includes moving the plurality of samples into the respective plurality of PCR reaction zones.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08  <p>US9738887 (Exhibit 31)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the

Claim	Claim Language	Infringement Evidence
		<p>detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> • US Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) • US Patent No. 9,738,887 at 15:31-35 (“The segment running to a detection chamber 163 functions to deliver a processed sample fluid to the detection chamber 117 with a reduced quantity of gas bubbles, and the segment running away from the detection chamber 164 functions to deliver a fluid away from the detection chamber 117.”) • US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth

Claim	Claim Language	Infringement Evidence
		<p>truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at Figs. 1J and 1K:  <p style="text-align: center;">FIG. 1J</p>  <p style="text-align: center;">FIG. 1K</p> <p style="text-align: right;">○ OCCLUDED</p>
33(d)	amplifying polynucleotides contained with the plurality of samples in the PCR reaction zones while thermal cycling the PCR reaction zones, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone.	<p>The accused workflow includes amplifying polynucleotides contained with the plurality of samples in the PCR reaction zones while thermal cycling the PCR reaction zones, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers

Claim	Claim Language	Infringement Evidence
		<p>market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.”</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”  <p><i>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</i></p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx

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		<p>Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.”</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

Claim	Claim Language	Infringement Evidence
		<div data-bbox="890 228 1793 776" data-label="Image"> </div> <ul style="list-style-type: none"> <li data-bbox="842 784 1921 1000"> <p>“A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p> <div data-bbox="905 1037 1614 1383" data-label="Image"> </div>

Claim	Claim Language	Infringement Evidence
		<p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module

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		<p>comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip,


Claim	Claim Language	Infringement Evidence
		<p>and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of

Claim	Claim Language	Infringement Evidence
		<p>nucleic acids.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) <p>U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate,

Claim	Claim Language	Infringement Evidence
		<p>comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,539,576 at 9:8-12 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies no.”) • U.S. Patent No. 9,539,576 at 12:59-64 (“Upon completion of Block S240, individual heater-sensor dies of the set of heater-sensor dies can be coupled to one or multiple electronics substrates in order to provide uniform heating of individual sample containers with independent control of heating parameters provided at each of the set of heater-sensor dies.”)

EXHIBIT 37

U.S. Patent No. 8,323,900 Infringement Chart


Claim	Claim Language	Infringement Evidence
1(a)	An apparatus, comprising:	<p>To the extent the preamble is limiting, the accused instrument is an apparatus.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p>  <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited</p>

Claim	Claim Language	Infringement Evidence
		<p>May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of

Claim	Claim Language	Infringement Evidence
		<p>the instrument with touchscreen computer, accessories, and reagents and consumables.”</p> <ul style="list-style-type: none"> • “NeuMoDx™ Molecular Systems are versatile; in addition to IVD tests, our system can also be used as an open system to process Laboratory Developed Tests (LDTs) that have been created and validated by your lab.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> • At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”)
1(b)	a plurality of multi-lane microfluidic cartridges, each lane comprising a PCR reaction zone;	<p>The accused apparatus comprises a plurality of multi-lane microfluidic cartridges, each lane comprising a PCR reaction zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • at 4:55-5:00 (showing a plurality of multi-lane cartridges in the accused apparatus)

Claim	Claim Language	Infringement Evidence
		  <p data-bbox="793 1162 1900 1300"> <i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16) </p> <ul data-bbox="842 1308 1892 1408" style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

Claim	Claim Language	Infringement Evidence
		<div data-bbox="890 233 1793 776" data-label="Image"> </div> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

Claim	Claim Language	Infringement Evidence
		 <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized

Claim	Claim Language	Infringement Evidence
		<p>reagents.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p>“Patents”, http://www.neumodx.com/patents/, demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 9,539,576; 9,637,775; and 10,093,963 (Exhibit 15)</p>

Claim	Claim Language	Infringement Evidence										
		<div><div>PATENTS</div><table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.</td></tr></table></div> <div>US9403165 (Exhibit 27)<ul style="list-style-type: none">Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent</div>	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636.	XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.
Product	Patents											
CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.											
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EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636.											
XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.											

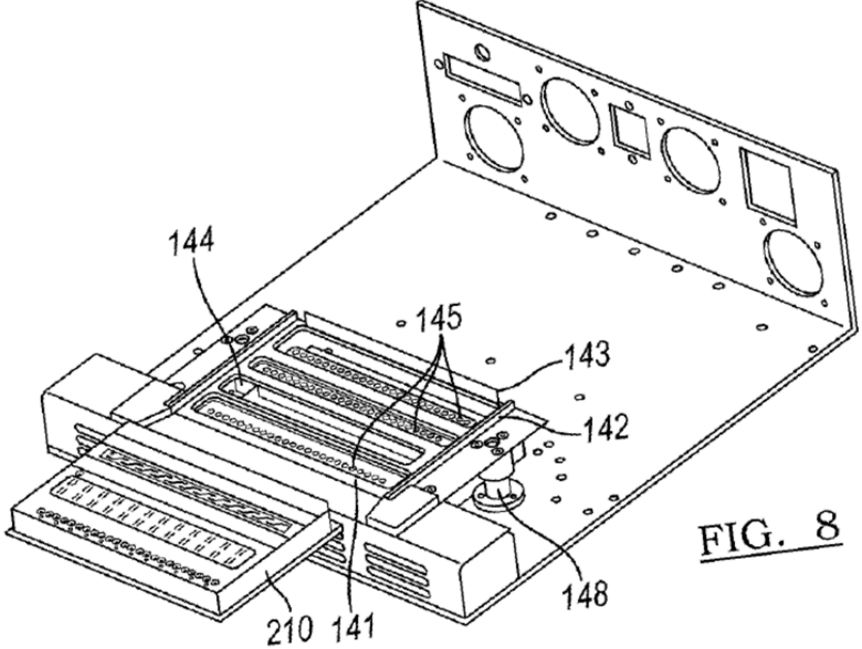
Claim	Claim Language	Infringement Evidence
		<p>port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular

Claim	Claim Language	Infringement Evidence
		<p>diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing

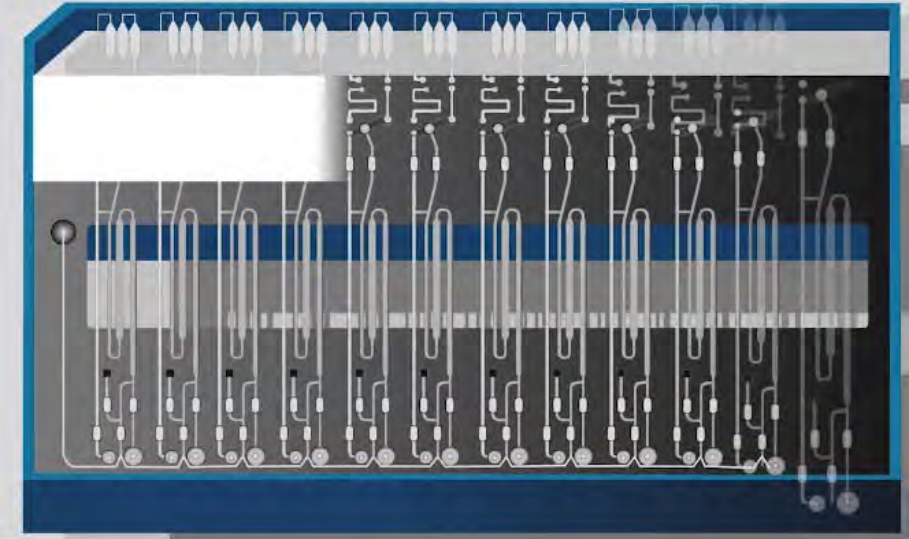
Claim	Claim Language	Infringement Evidence
		<p>and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis.

Claim	Claim Language	Infringement Evidence
		<p>Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)</p>
1(c)	a plurality of receiving bays, each receiving bay configured to receive one of the plurality of microfluidic cartridges;	<p>The accused apparatus comprises a plurality of receiving bays, each receiving bay configured to receive one of the plurality of microfluidic cartridges.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • at 4:55-5:00

Claim	Claim Language	Infringement Evidence
		  <p data-bbox="793 1122 1115 1159">US9050594 (Exhibit 24)</p> <ul data-bbox="842 1166 1921 1414" style="list-style-type: none"> • Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator

Claim	Claim Language	Infringement Evidence
		<p>configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 2:6-7 (“FIG. 8 depicts an embodiment of a microfluidic cartridge and an embodiment of a cartridge platform.”) • U.S. Patent No. 9,050,594 at Fig. 8  <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 7:53-8:35 “As shown in FIG. 9A, the cartridge receiving module 140 of the molecular diagnostic module 130 comprises a cartridge platform 141 including a cartridge loading guiderail 142, a cartridge

Claim	Claim Language	Infringement Evidence
		<p>stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145; a linear actuator 146 configured to displace a microfluidic cartridge 210 resting on the cartridge platform 141, and a set of springs 148 coupled to the cartridge platform 141. The cartridge receiving module 140 thus functions to receive, align, and compress a microfluidic cartridge 210 for processing of a biological sample according to a molecular diagnostic assay protocol.... The cartridge platform 141 includes a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145, and functions to receive and align a microfluidic cartridge 210, while providing access to the microfluidic cartridge 210 by a magnet 160 and a valve actuation subsystem 170. As shown in FIG. 8, an embodiment of the cartridge platform 141 includes a pair of parallel cartridge loading guiderails 142, initiating at a pair of inwardly tapering protrusions configured to guide a microfluidic cartridge toward the pair of parallel cartridge loading guiderails 142, and spanning two short edges of the cartridge platform 141. The embodiment of the cartridge platform 141 also includes a cartridge stop 143 comprising a vertical tab oriented perpendicular to the cartridge loading guiderails 142, and spanning a long edge of the cartridge platform. Preferably, the cartridge loading guiderails 142 and the cartridge stop 143 are configured such that a microfluidic cartridge 210 slides between the cartridge loading guiderails 142 and hits the cartridge stop 143 to signal proper alignment.”</p>
1(d)	each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto,	<p>In the accused apparatus, each PCR reaction zone comprises a separately controllable heat source thermally coupled thereto.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

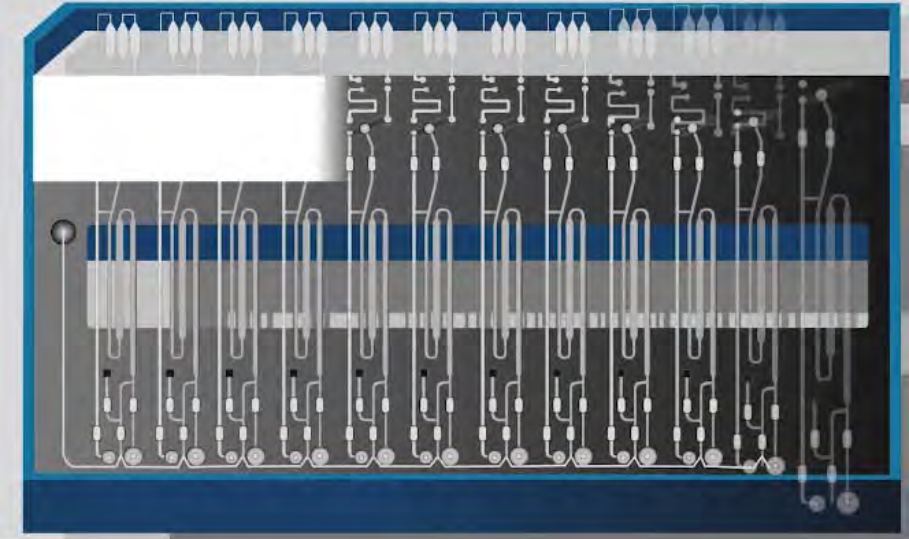
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 813 1877 889"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="842 894 1921 1219" style="list-style-type: none"> • “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p data-bbox="793 1260 1108 1292">US9050594 (Exhibit 24)</p> <ul data-bbox="842 1300 1921 1401" style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic

Claim	Claim Language	Infringement Evidence
		<p>bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-

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		<p>sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12

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		<p>different pathways for sample processing.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”) <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of

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		<p>the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <p>U.S. Patent No. 9,499,896 at 12:15-20 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies 110.”)</p>
1(e)	wherein the heat source thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and	<p>In the accused apparatus, each PCR reaction zone comprises a separately controllable heat source thermally coupled thereto wherein the heat source thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

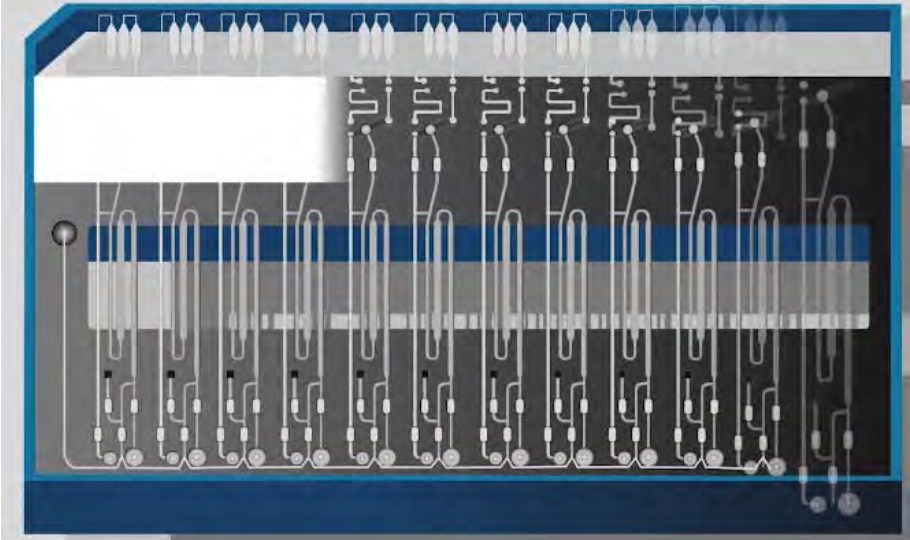
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 813 1877 889"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="842 894 1923 1219" style="list-style-type: none"> • “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p data-bbox="793 1260 1110 1292">US9050594 (Exhibit 24)</p> <ul data-bbox="842 1300 1923 1403" style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic

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		<p>bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-

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		<p>sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12

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		<p>different pathways for sample processing.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”) <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of

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		the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.
1(f)	maintains a substantially uniform temperature throughout the PCR reaction zone during each cycle;	<p>In the accused apparatus, each PCR reaction zone comprises a separately controllable heat source thermally coupled thereto wherein the heat source thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and maintains a substantially uniform temperature throughout the PCR reaction zone during each cycle.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

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		 <ul style="list-style-type: none"> <p>“A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p>

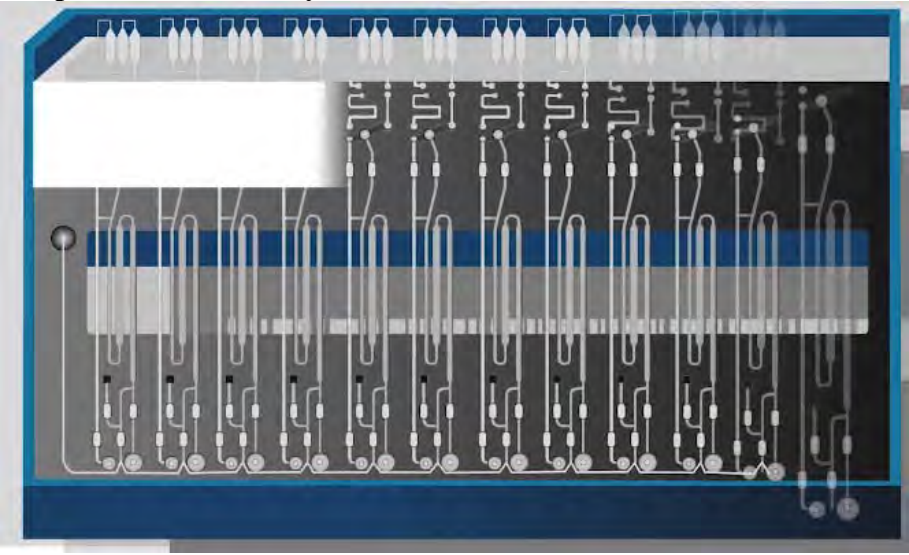
Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 228 1612 574" data-label="Image"> </div> <p data-bbox="793 613 1877 683"><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="842 695 1923 1019" style="list-style-type: none"> • “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p data-bbox="793 1057 1108 1089">US9050594 (Exhibit 24)</p> <ul data-bbox="842 1101 1923 1421" style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet

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		<p>receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module

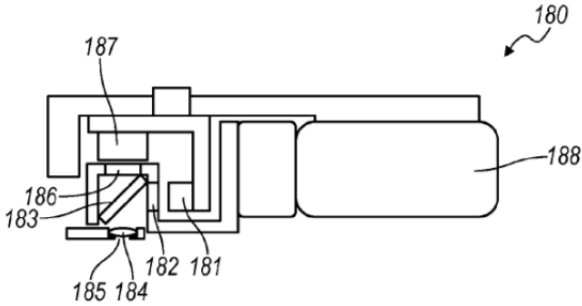
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		<p>comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic

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		<p>pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers. U.S. Patent No. 9,499,896 at 2:33-48 “The system 100 functions to enable

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		<p>rapid thermal cycling of samples while providing uniform heating and preventing signal drift. In specific applications, the system 100 can be used to rapidly and controllably thermocycle nucleic acid samples during performance of molecular diagnostic amplification techniques (e.g., PCR, RT-PCR), signal amplification techniques (e.g., bDNA, hybrid capture), and analytical techniques (e.g., gel electrophoresis, mass spectrometry). The system 100 can also provide rapid thermocycling without significant power requirements, ensure a closer correlation between the actual heating temperature and the temperature set-point by implementing an integrated heater-sensor die, and controllably and individually heat small sample volumes (e.g., picoliters, nanoliters) based upon a microfabrication technique that also enables mass production of the system 100.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,499,896 at 2:61-3:3 (“The set of heater-sensor dies 110 functions to controllably heat individual sample volumes. Preferably, each heater sensor die 111 is a thin-film die that can be deposited onto another substrate (e.g., silicon, glass substrate) that can be packaged onto an electronics substrate 140 (e.g., printed circuit board, PCB); however, each heater-sensor die 111 can alternatively comprise any suitable geometry and/or configuration that enables controlled, uniform, and rapid heating of a detection chamber in thermal communication with the heater-sensor die 111.”) • U.S. Patent No. 9,499,896 at 3:23-27 (“Preferably, each heater-sensor die 111 in the set of heater sensor dies 110 comprises an assembly including: a first insulating layer 112a that functions to provide an insulating barrier to isolate the heaters and sensors and a heating region 113 that functions to provide uniform sample heating.”)
1(g)	a detector configured to detect the presence of an amplification product in one or more PCR reaction zones; and	<p>The accused apparatus comprises a detector configured to detect the presence of an amplification product in one or more PCR reaction zones.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO </p>

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		<p>NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the

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		<p>heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,499,896 at 2:33-48 “The system 100 functions to enable rapid thermal cycling of samples while providing uniform heating and preventing signal drift. In specific applications, the system 100 can be used to rapidly and controllably thermocycle nucleic acid samples during performance of molecular diagnostic amplification techniques (e.g., PCR, RT-PCR), signal amplification techniques (e.g., bDNA, hybrid capture), and analytical techniques (e.g., gel electrophoresis, mass spectrometry). The system 100 can also provide rapid thermocycling without significant power requirements, ensure a closer correlation between the actual heating temperature and the temperature set-point by implementing an integrated heater-sensor die, and controllably and individually heat small sample volumes (e.g., picoliters, nanoliters) based upon a microfabrication technique that also enables mass production of the system 100.”) • U.S. Patent No. 9,499,896 at 2:61-3:3 (“The set of heater-sensor dies 110 functions to controllably heat individual sample volumes. Preferably, each heater sensor die 111 is a thin-film die that can be deposited onto another substrate (e.g., silicon, glass substrate) that can be packaged onto an electronics substrate 140 (e.g., printed circuit board, PCB); however, each heater-sensor die 111 can alternatively comprise any suitable geometry and/or configuration that enables controlled, uniform, and rapid heating of a detection chamber in thermal communication with the heater-sensor die


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		<p>111.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 3:23-27 (“Preferably, each heater-sensor die 111 in the set of heater sensor dies 110 comprises an assembly including: a first insulating layer 112a that functions to provide an insulating barrier to isolate the heaters and sensors and a heating region 113 that functions to provide uniform sample heating.”)  <p>FIG. 12A</p>
1(h)	a processor coupled to the detector and the heat sources, configured to control heating of one or more PCR reaction zones by the heat sources.	<p>The accused apparatus comprises a processor coupled to the detector and the heat sources, configured to control heating of one or more PCR reaction zones by the heat sources.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully

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		<p>automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-</p>


Claim	Claim Language	Infringement Evidence
		<p>young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”) <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of

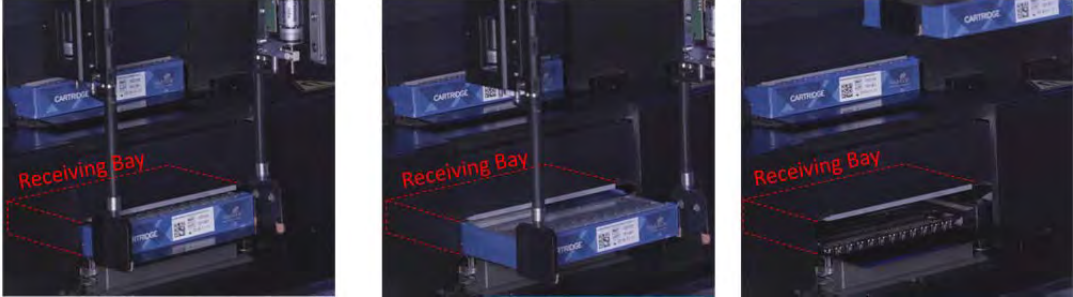
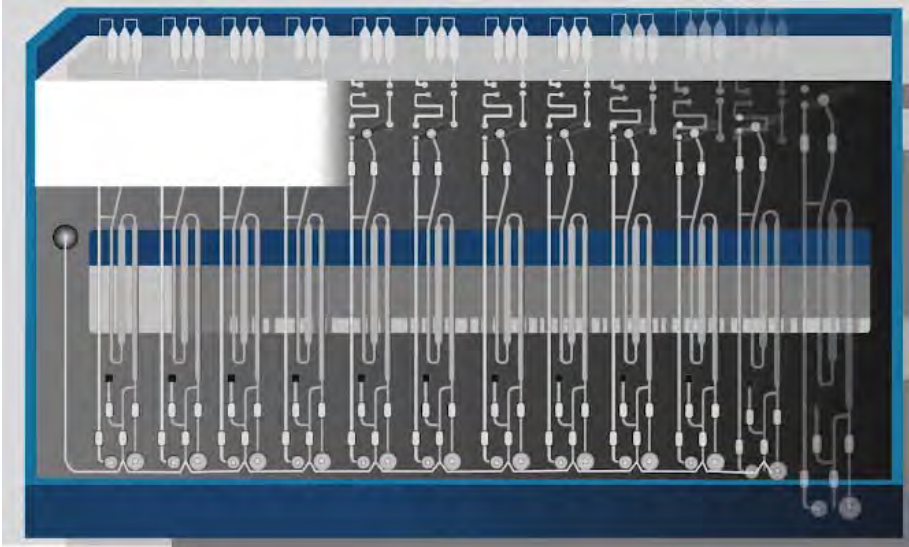
Claim	Claim Language	Infringement Evidence
		<p>detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers. U.S. Patent No. 9,499,896 at 2:21-32 (“As shown in FIGS. 1A and 1B, an embodiment of a system 100 for thermocycling biological samples within detection chambers comprises: a set of heater-sensor dies 110; an electronics substrate 140 that couple the set of heater-sensor dies to a controller; a set of heat sink supports 150 coupled to at least one of the electronics substrate and the set of heater-sensor dies; and a set of elastic elements 160 coupled to the

Claim	Claim Language	Infringement Evidence
		<p>electronics substrate and configured to bias each of the set of heater-sensor dies against a detection 30 chamber. In some embodiments, the system 100 further comprises a controller 165 and/or a cooling subsystem 170 configured to actively cool the system 100.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,499,896 at 9:11-19 (“As shown in FIGS. 1, 4A-4B, and 7A-7C, the system 100 can further comprise an electronics substrate 140 configured to couple heating and sensing elements of the set of heater-sensor dies to a controller 165, a set of heat-sink supports 150 configured to facilitate heat dissipation within the system 100, a set of elastic elements 160 configured to bias the set of heater-sensor dies 110 against detection chambers for sample processing, and can additionally comprise the controller 165 and/or a cooling subsystem 170.”) • U.S. Patent No. 9,499,896 at 12:20-31 (“In a specific example, the controller 165 comprises a Yokogawa UT750 PID controller, an Arduino UNO R3 microcontroller configured to cycle the UT750 through temperature stages and to control temperature holding, a resistance-to-voltage conversion circuit, and two power supplies—a first power supply configured to supply power to the set of heater-sensor dies 110 and a second power supply configured to supply voltage to the resistance-to-voltage conversion circuit. In the specific example, the controller 165 comprises a resistance-to-voltage conversion circuit because the UT750 PID controller requires voltage as an input for PID control.”) • U.S. Patent No. 9,499,896 at 11:63-12:4 “As shown in FIGS. 1A and 1B, the system 100 can further comprise a controller 165, which functions to automate and/or control heating parameters provided by the set of heater-sensor dies 110. The controller 165 can further be configured to provide heat parameter output commands to the heating element(s) 114, and/or configured to receive communication of heating parameters (e.g., detected temperatures) sensed at the sensing element(s) 115 of the system 100.”)
7(a)	A device for carrying out PCR on a plurality of samples, the	To the extent the preamble is limiting, the accused instrument is a device.

Claim	Claim Language	Infringement Evidence
	device comprising:	<p data-bbox="793 233 1921 302"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p> <div data-bbox="793 302 1843 1114">  </div> <p data-bbox="793 1149 1921 1224"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="842 1230 1892 1305" style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p data-bbox="793 1338 1921 1406"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “NeuMoDx™ Molecular Systems are versatile; in addition to IVD tests, our system can also be used as an open system to process Laboratory Developed Tests (LDTs) that have been created and validated by your lab.”

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”)
7(b)	a plurality of multi-lane microfluidic cartridges, each lane comprising a PCR reaction zone;	<p>The accused device comprises a plurality of multi-lane microfluidic cartridges, each lane comprising a PCR reaction zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> at 4:55-5:00 (showing a plurality of multi-lane cartridges in the accused apparatus) 

Claim	Claim Language	Infringement Evidence
		<div data-bbox="798 232 1864 527">  </div> <p data-bbox="793 602 1900 743"> <i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16) </p> <ul data-bbox="842 751 1892 857" style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59 <div data-bbox="890 857 1793 1401">  </div>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.” <div data-bbox="888 565 1648 1036" data-label="Image"> </div> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”.


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		<p>The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System.... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx


Claim	Claim Language	Infringement Evidence
		<p>System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.”</p> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic

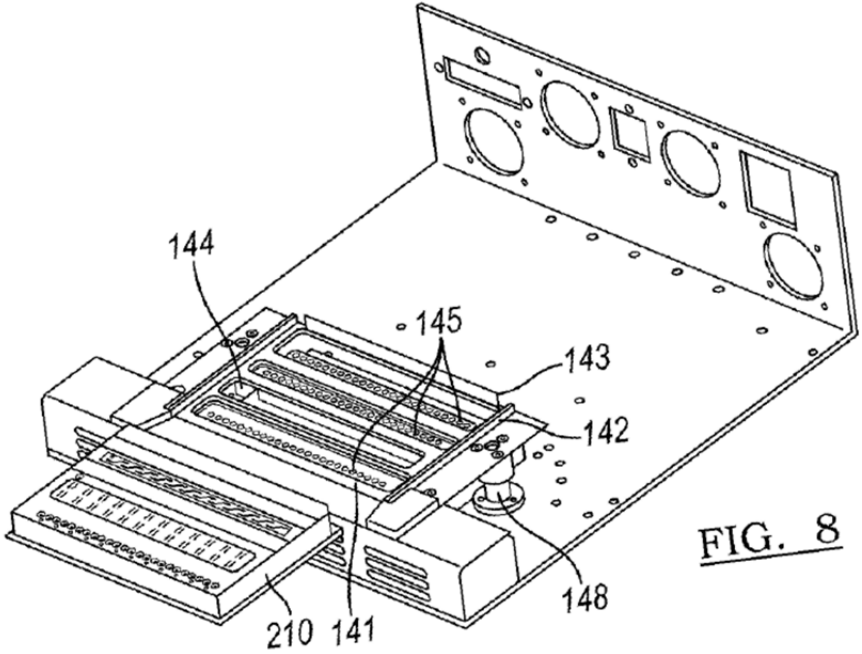
Claim	Claim Language	Infringement Evidence
		<p>bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-

Claim	Claim Language	Infringement Evidence
		<p>sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system

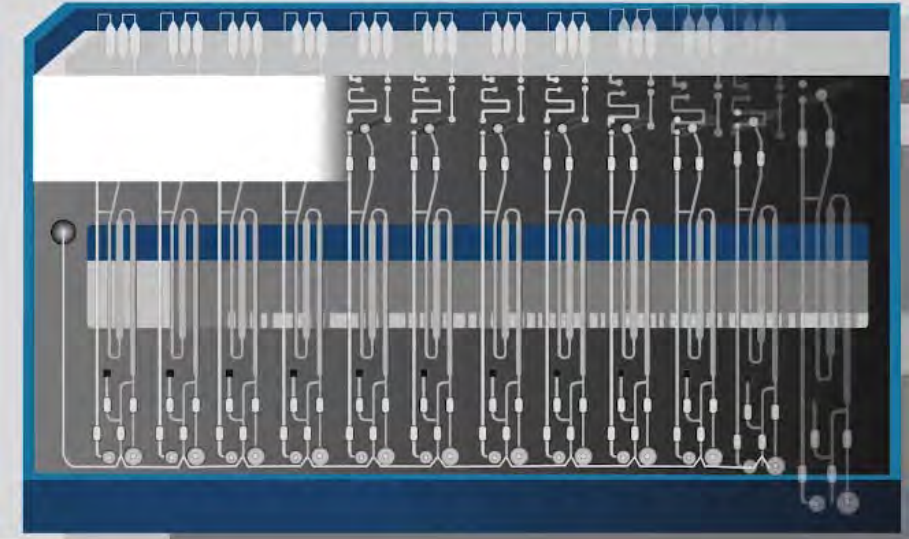
Claim	Claim Language	Infringement Evidence
		<p>configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)
7(c)	a plurality of receiving bays, each receiving bay configured to	The accused device comprises a plurality of receiving bays, each receiving bay configured to receive one of the plurality of microfluidic cartridges.

Claim	Claim Language	Infringement Evidence
	receive one of the plurality of microfluidic cartridges;	<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ TECHNOLOGY” hyperlink at https://player.vimeo.com/video/281470603. (Exhibit 17)</p> <ul style="list-style-type: none"> • at 4:55-5:00 

Claim	Claim Language	Infringement Evidence
		 <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. U.S. Patent No. 9,050,594 at 2:6-7 (“FIG. 8 depicts an embodiment of a microfluidic cartridge and an embodiment of a cartridge platform.”) U.S. Patent No. 9,050,594 at Fig. 8

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1648 738 1795 803">FIG. 8</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 7:53-8:35 “As shown in FIG. 9A, the cartridge receiving module 140 of the molecular diagnostic module 130 comprises a cartridge platform 141 including a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145; a linear actuator 146 configured to displace a microfluidic cartridge 210 resting on the cartridge platform 141, and a set of springs 148 coupled to the cartridge platform 141. The cartridge receiving module 140 thus functions to receive, align, and compress a microfluidic cartridge 210 for processing of a biological sample according to a molecular diagnostic assay protocol.... The cartridge platform 141 includes a cartridge loading guiderail 142, a cartridge stop 143, a magnet receiving slot 144, and a set of valve actuation slots 145, and functions to receive and align a microfluidic cartridge 210, while providing access to the microfluidic cartridge 210 by a magnet 160 and a valve actuation subsystem 170. As shown in FIG. 8, an embodiment of the cartridge

Claim	Claim Language	Infringement Evidence
		<p>platform 141 includes a pair of parallel cartridge loading guiderails 142, initiating at a pair of inwardly tapering protrusions configured to guide a microfluidic cartridge toward the pair of parallel cartridge loading guiderails 142, and spanning two short edges of the cartridge platform 141. The embodiment of the cartridge platform 141 also includes a cartridge stop 143 comprising a vertical tab oriented perpendicular to the cartridge loading guiderails 142, and spanning a long edge of the cartridge platform. Preferably, the cartridge loading guiderails 142 and the cartridge stop 143 are configured such that a microfluidic cartridge 210 slides between the cartridge loading guiderails 142 and hits the cartridge stop 143 to signal proper alignment.”</p>
7(d)	a separately controllable heat source thermally coupled to each PCR reaction zone,	<p>The accused device comprises a separately controllable heat source thermally coupled to each PCR reaction zone.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 813 1877 889"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> <li data-bbox="842 894 1923 1219">• “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p data-bbox="793 1260 1108 1292">US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> <li data-bbox="842 1300 1923 1403">• Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic

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		<p>bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-

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		<p>sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12

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		<p>different pathways for sample processing.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”) <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of

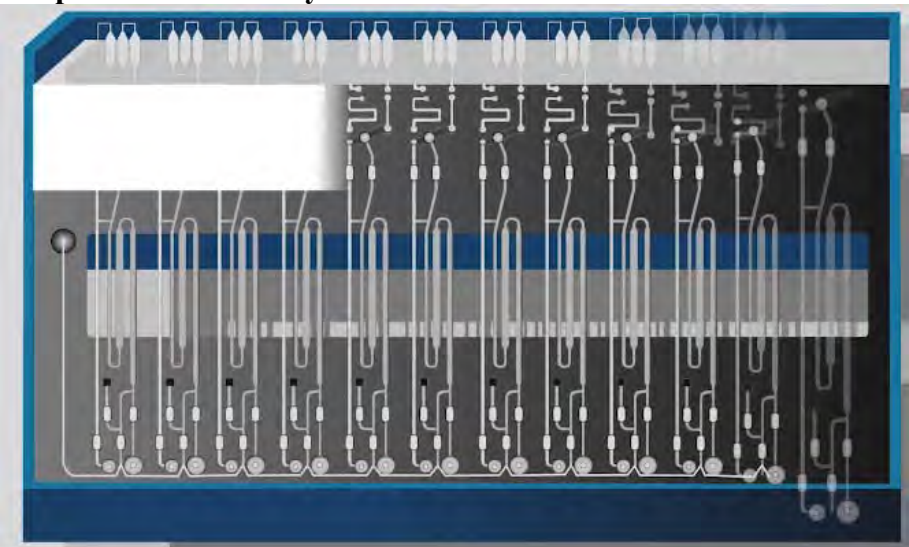
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		<p>the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <p>U.S. Patent No. 9,499,896 at 12:15-20 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies 110.”)</p>
7(e)	wherein the heat source is configured to thermal cycle the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and	<p>In the accused device, the heat source is configured to thermal cycle the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

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		<div data-bbox="890 233 1793 776" data-label="Image"> </div> <p data-bbox="793 813 1877 889"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="842 894 1919 1219" style="list-style-type: none"> • “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p data-bbox="793 1260 1108 1292">US9050594 (Exhibit 24)</p> <ul data-bbox="842 1300 1919 1403" style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic

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		<p>bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-

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		<p>sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12

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		<p>different pathways for sample processing.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”) <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of

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		<p>the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p>
7(f)	to maintain a substantially uniform temperature throughout the PCR reaction zone during each cycle;	<p>In the accused device, the heat source is configured to thermal cycle the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and to maintain a substantially uniform temperature throughout the PCR reaction zone during each cycle</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59 

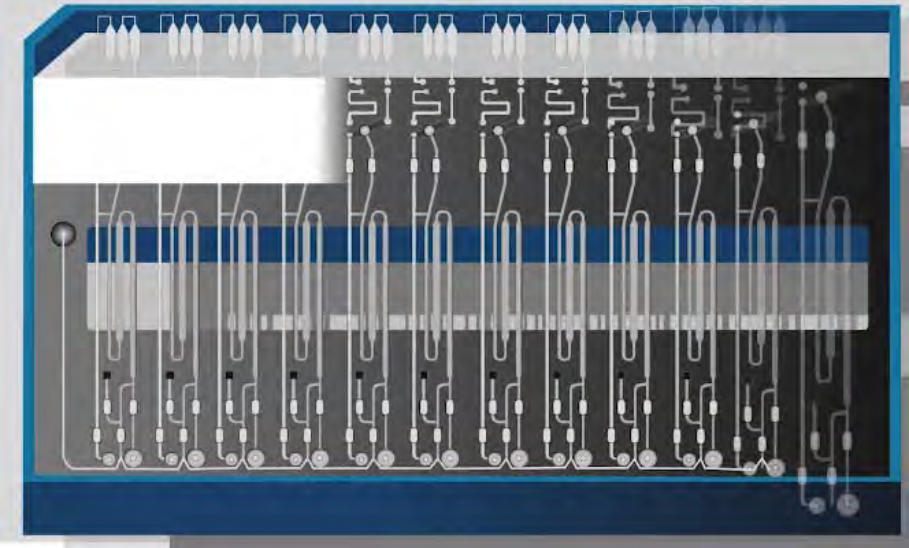
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		<ul style="list-style-type: none"> <p>“A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p> <div data-bbox="905 553 1612 901" data-label="Image"> </div> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> <p>“NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.”</p>

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		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic

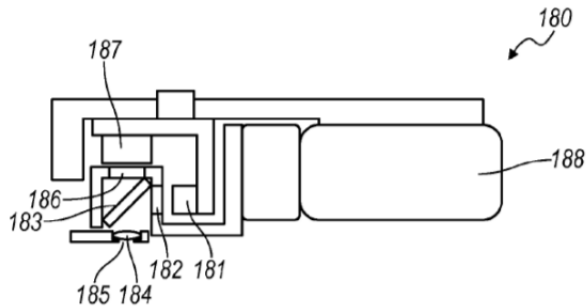
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		<p>module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157,

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		<p>which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”) <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and

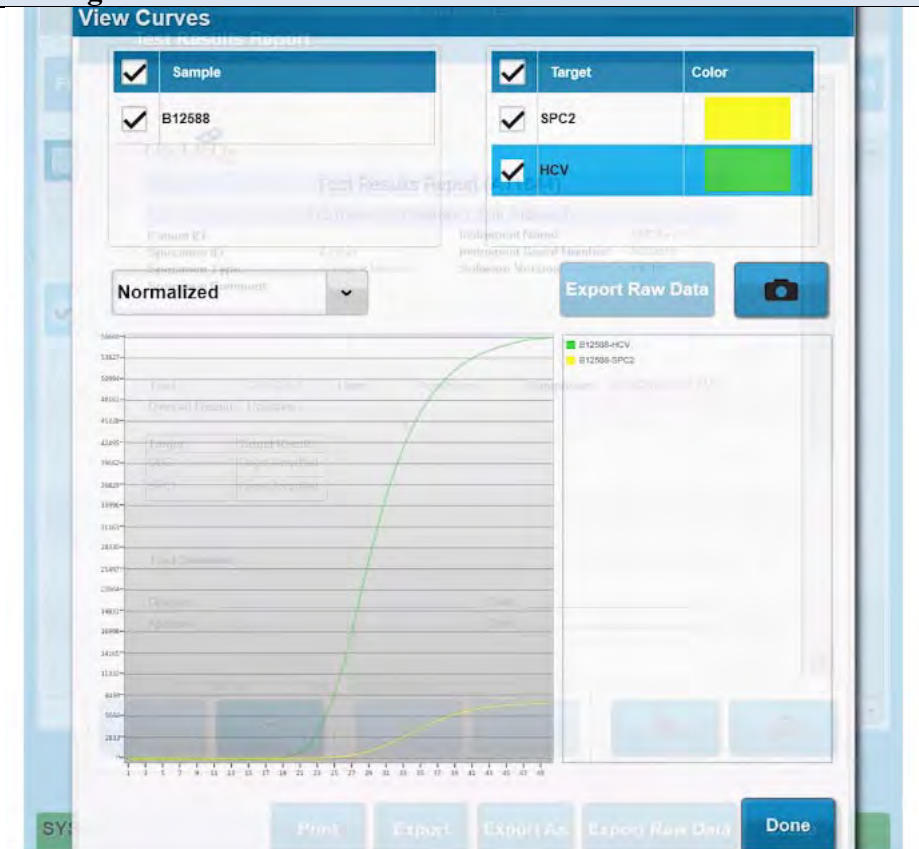
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		<p>associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,499,896 at 2:33-48 “The system 100 functions to enable rapid thermal cycling of samples while providing uniform heating and preventing signal drift. In specific applications, the system 100 can be used to rapidly and controllably thermocycle nucleic acid samples during performance of molecular diagnostic amplification techniques (e.g., PCR, RT-PCR), signal amplification techniques (e.g., bDNA, hybrid capture), and analytical techniques (e.g., gel electrophoresis, mass spectrometry). The system 100 can also provide rapid thermocycling without significant power requirements, ensure a closer correlation between the actual heating temperature and the temperature set-point by implementing an integrated heater-sensor die, and controllably and individually heat small sample volumes (e.g., picoliters, nanoliters) based upon a microfabrication technique that also enables mass production of the system 100.”) • U.S. Patent No. 9,499,896 at 2:61-3:3 (“The set of heater-sensor dies 110 functions to controllably heat individual sample volumes. Preferably, each heater sensor die 111 is a thin-film die that can be deposited onto another substrate (e.g., silicon, glass substrate) that can be packaged onto an electronics substrate 140 (e.g., printed circuit board, PCB); however, each heater-sensor die 111 can alternatively comprise any suitable geometry and/or configuration that enables controlled, uniform, and rapid heating of a detection chamber in thermal communication with the heater-sensor die 111.”) • U.S. Patent No. 9,499,896 at 3:23-27 (“Preferably, each heater-sensor die 111 in

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		the set of heater sensor dies 110 comprises an assembly including: a first insulating layer 112a that functions to provide an insulating barrier to isolate the heaters and sensors and a heating region 113 that functions to provide uniform sample heating. ")
7(g)	a detector configured to detect the presence of an amplification product in one or more PCR reaction zones;	<p>The accused device comprises a detector configured to detect the presence of an amplification product in one or more PCR reaction zones.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59 

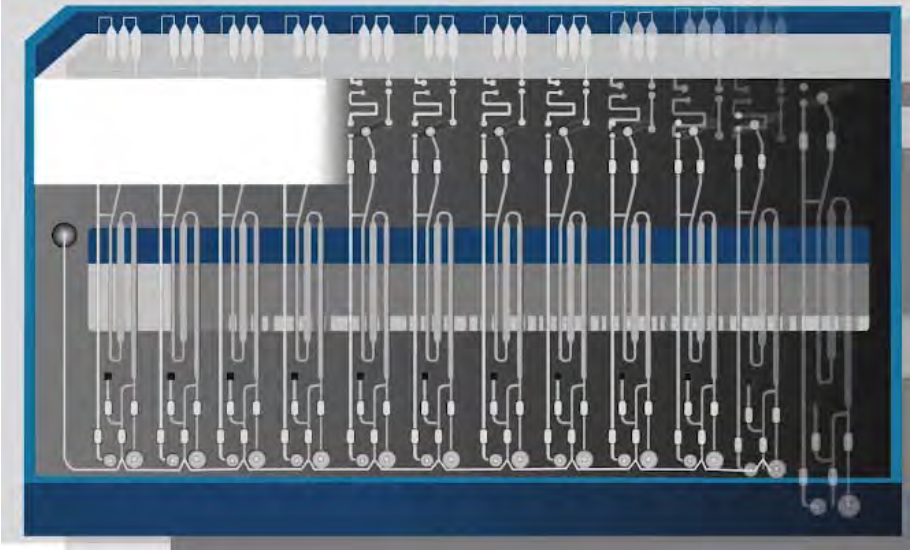
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		<p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers. • U.S. Patent No. 9,499,896 at 2:33-48 “The system 100 functions to enable rapid thermal cycling of samples while providing uniform heating and preventing signal drift. In specific applications, the system 100 can be used to rapidly and controllably thermocycle nucleic acid samples during performance of molecular diagnostic amplification techniques (e.g., PCR, RT-PCR), signal amplification techniques (e.g., bDNA, hybrid capture), and analytical techniques (e.g., gel electrophoresis, mass spectrometry). The system 100 can also provide rapid thermocycling without significant power requirements, ensure a closer correlation between the actual heating temperature and the temperature set-point by implementing an integrated heater-sensor die, and controllably and individually heat small sample volumes (e.g., picoliters, nanoliters) based upon

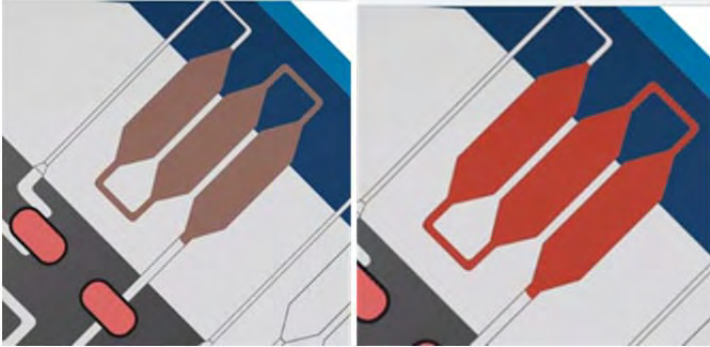
Claim	Claim Language	Infringement Evidence
		<p>a microfabrication technique that also enables mass production of the system 100.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 2:61-3:3 (“The set of heater-sensor dies 110 functions to controllably heat individual sample volumes. Preferably, each heater sensor die 111 is a thin-film die that can be deposited onto another substrate (e.g., silicon, glass substrate) that can be packaged onto an electronics substrate 140 (e.g., printed circuit board, PCB); however, each heater-sensor die 111 can alternatively comprise any suitable geometry and/or configuration that enables controlled, uniform, and rapid heating of a detection chamber in thermal communication with the heater-sensor die 111.”) U.S. Patent No. 9,499,896 at 3:23-27 (“Preferably, each heater-sensor die 111 in the set of heater sensor dies 110 comprises an assembly including: a first insulating layer 112a that functions to provide an insulating barrier to isolate the heaters and sensors and a heating region 113 that functions to provide uniform sample heating.”)  <p style="text-align: center;">FIG. 12A</p>
7(h)	a processor coupled to the detector	<p>The accused device comprises a processor coupled to the detector.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited</p>


Claim	Claim Language	Infringement Evidence
		<p>May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

Claim	Claim Language	Infringement Evidence
		 <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

Claim	Claim Language	Infringement Evidence
		<div data-bbox="884 267 1648 738" data-label="Image"> </div> <p data-bbox="793 833 1665 865">40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul data-bbox="842 873 1913 1157" style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p data-bbox="793 1203 1902 1341"><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul data-bbox="842 1349 1902 1414" style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access

Claim	Claim Language	Infringement Evidence
		<p>processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 613 1877 683"><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="842 695 1915 873" style="list-style-type: none"> • “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.”
7(i)	and a plurality of the separately controllable heat sources, configured to control heating of one or more PCR reaction zones by one or more of the plurality of separately controllable heat sources; and	<p data-bbox="793 915 1915 1019">The accused device comprises a plurality of the separately controllable heat sources, configured to control heating of one or more PCR reaction zones by one or more of the plurality of separately controllable heat sources.</p> <p data-bbox="793 1101 1465 1133"><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul data-bbox="842 1138 1885 1203" style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

Claim	Claim Language	Infringement Evidence
		 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

Claim	Claim Language	Infringement Evidence
		<div data-bbox="890 233 1793 776" data-label="Image"> </div> <ul style="list-style-type: none"> <li data-bbox="842 786 1923 1000"> <p>“A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p> <div data-bbox="905 1039 1612 1383" data-label="Image"> </div>

Claim	Claim Language	Infringement Evidence
		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic


Claim	Claim Language	Infringement Evidence
		<p>acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads,

Claim	Claim Language	Infringement Evidence
		<p>isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently

Claim	Claim Language	Infringement Evidence
		<p>of the other nucleic acid reagent mixtures.”)</p> <ul style="list-style-type: none"> •
7(j)	an input device coupled to the processor and configured to permit concurrent or consecutive control of the plurality of multi-lane microfluidic cartridges	<p>The accused device comprises an input device coupled to the processor and configured to permit concurrent or consecutive control of the plurality of multi-lane microfluidic cartridges.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated

Claim	Claim Language	Infringement Evidence						
		<p>extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.”</p> <ul style="list-style-type: none">• “NeuMoDx™ Molecular Systems are versatile; in addition to IVD tests, our system can also be used as an open system to process Laboratory Developed Tests (LDTs) that have been created and validated by your lab.” <p>JFO_2018-10-25_8009-Rev-B_NeuMoDx-96-Spec-Sheet.pdf (Exhibit 21)</p> <table><tr><td>Sample capacity</td><td>96 initial load; Continuous, Random-Access Thereafter</td></tr><tr><td>Reagent capacity</td><td>320 initial load; Continuous, Random-Access Thereafter</td></tr></table> <table><tr><td>Operational flexibility</td><td>Continuous Random-Access Perform LDT Qualitative and Quantitative assays simultaneously on demand⁴ Onboard inventory management Simultaneous use of multiple tube types and sizes Flexible specimen tube compatibility<ul style="list-style-type: none">• Diameter: 11 mm - 18 mm• Height: 60 mm – 120 mm</td></tr></table> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX , http://www.neumodx.com/product/neumodx-288/, last visited June 4, 2019 (Exhibit 13)</p> <ul style="list-style-type: none">• “The NeuMoDx™ 288 Molecular System is intended for in vitro diagnostic (IVD) use in performing NeuMoDx™ validated nucleic acid testing in clinical laboratories. The NeuMoDx™ 288 Molecular System is capable of automated extraction and isolation of nucleic acids from multiple specimen types, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The system is capable of providing functionality to enable laboratories to develop qualitative and quantitative tests, which use NeuMoDx™ -provided consumables and reagents.• Instrument Includes:<ul style="list-style-type: none">○ Uninterruptible power supply (UPS)	Sample capacity	96 initial load; Continuous, Random-Access Thereafter	Reagent capacity	320 initial load; Continuous, Random-Access Thereafter	Operational flexibility	Continuous Random-Access Perform LDT Qualitative and Quantitative assays simultaneously on demand ⁴ Onboard inventory management Simultaneous use of multiple tube types and sizes Flexible specimen tube compatibility <ul style="list-style-type: none">• Diameter: 11 mm - 18 mm• Height: 60 mm – 120 mm
Sample capacity	96 initial load; Continuous, Random-Access Thereafter							
Reagent capacity	320 initial load; Continuous, Random-Access Thereafter							
Operational flexibility	Continuous Random-Access Perform LDT Qualitative and Quantitative assays simultaneously on demand ⁴ Onboard inventory management Simultaneous use of multiple tube types and sizes Flexible specimen tube compatibility <ul style="list-style-type: none">• Diameter: 11 mm - 18 mm• Height: 60 mm – 120 mm							


Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> ○ Handheld barcode scanner ○ Keyboard and mouse ○ NeuMoDx™ Biohazard Waste Container ○ Carriers ○ Test Strip Carrier (6) ○ Buffer Carrier (2) ○ 32-tube Specimen Tube Carrier (9) ○ Tip, Extraction and Filter Carrier (2) ○ Cartridge Carrier (2)” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX , http://www.neumodx.com/product/neumodx-96/, last visited June 4, 2019 (Exhibit 14)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ 96 Molecular System is intended for in vitro diagnostic (IVD) use in performing NeuMoDx™ validated nucleic acid testing in clinical laboratories. The NeuMoDx™ 96 Molecular System is capable of automated extraction and isolation of nucleic acids from multiple specimen types, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The system is capable of providing functionality to enable laboratories to develop qualitative and quantitative tests, which use NeuMoDx™ provided consumables and reagents. • Instrument Includes: <ul style="list-style-type: none"> ○ Uninterruptible power supply (UPS) ○ Handheld barcode scanner ○ Keyboard and mouse ○ Biohazard Waste Bin ○ Biohazard Tip Waste Bin ○ Biohazard Waste Container ○ Carriers ○ Test Strip Carrier (4) ○ Buffer Carrier (1) ○ 32-tube Specimen Tube Carrier (3) ○ Tip, Extraction and Filter Carrier (1)

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Cartridge Carrier (1)”
20(a)	A method of carrying out PCR on a plurality of samples, the method comprising:	<p>To the extent the preamble is limiting, the accused workflow is a method of carrying out PCR on a plurality of samples.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p>  <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited</p>

Claim	Claim Language	Infringement Evidence
		<p>May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of

Claim	Claim Language	Infringement Evidence
		<p>the instrument with touchscreen computer, accessories, and reagents and consumables.”</p> <ul style="list-style-type: none"> • “NeuMoDx™ Molecular Systems are versatile; in addition to IVD tests, our system can also be used as an open system to process Laboratory Developed Tests (LDTs) that have been created and validated by your lab.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/dr-steven-young-video-testimonial/, hyperlink at https://youtu.be/vukP6gbLBYE. (Exhibit 32)</p> <ul style="list-style-type: none"> • At 2:58-3:18 (“There’s two systems that have been put into operation by NeuMoDx. One is the 288. It’s a high-throughput instrument, versus the 96, which is a lower throughput instrument. The advantage is that both systems use all of the same chemistry and all of the same hardware. Its just a smaller footprint.”)
20(b)	introducing the plurality of samples into a plurality of multi-lane microfluidic cartridges, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples;	<p>The accused workflow comprises introducing the plurality of samples into a plurality of multi-lane microfluidic cartridges, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The liquid handling robot aspirates the PCR-ready solution and transfers it back to the cartridge where it dispenses into the same P-port from which the sample was aspirated.” <i>Id.</i> at 3:47-3:57

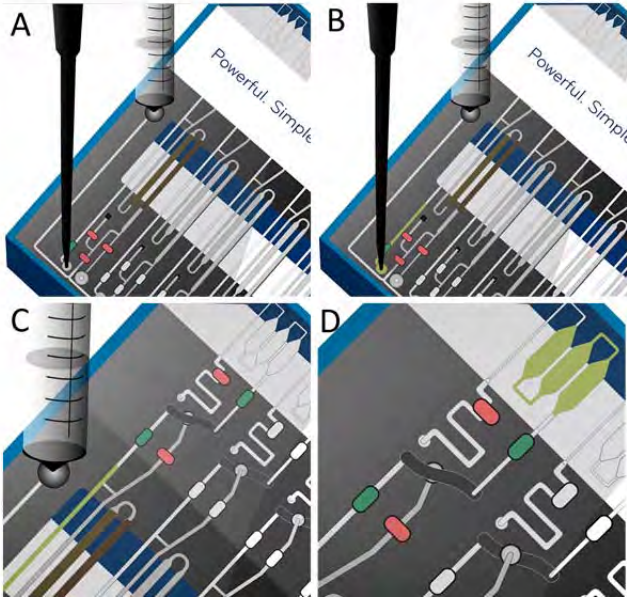
Claim	Claim Language	Infringement Evidence
		

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 935 1108 967">US9101930 (Exhibit 25)</p> <ul data-bbox="842 976 1921 1408" style="list-style-type: none"> • Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the

Claim	Claim Language	Infringement Evidence
		<p>intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> Claim 11. The cartridge of claim 10, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, wherein the first fluidic pathway is substantially identical to the second fluidic pathway, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second

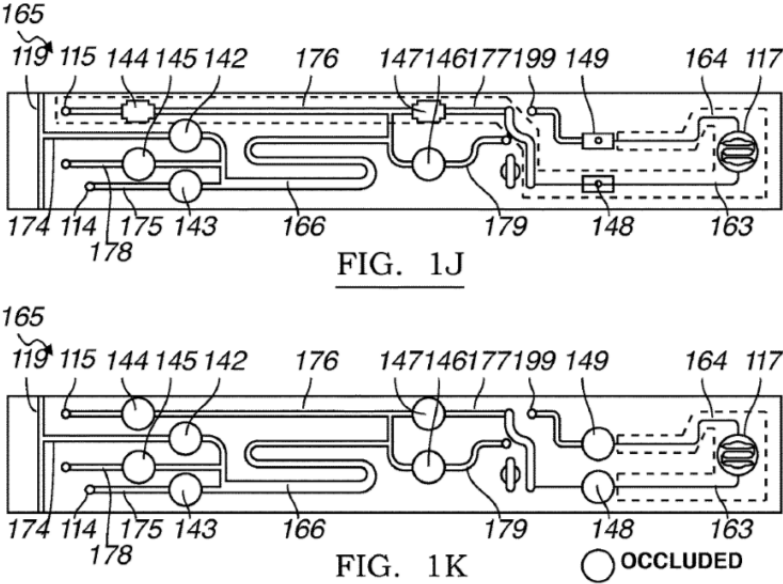
Claim	Claim Language	Infringement Evidence
		<p>sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward


Claim	Claim Language	Infringement Evidence
		<p>the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but

Claim	Claim Language	Infringement Evidence
		alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)
20(c)	moving the plurality of samples into the respective plurality of PCR reaction zones; and	<p>The accused workflow comprises moving the plurality of samples into the respective plurality of PCR reaction zones.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

Claim	Claim Language	Infringement Evidence
		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion

Claim	Claim Language	Infringement Evidence
		<p>positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> • US9738887 (Exhibit 31) at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) • US9738887 (Exhibit 31) at 15:31-35 (“The segment running to a detection chamber 163 functions to deliver a processed sample fluid to the detection chamber 117 with a reduced quantity of gas bubbles, and the segment running away from the detection chamber 164 functions to deliver a fluid away from the detection chamber 117.”) • US9738887 (Exhibit 31) at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which

Claim	Claim Language	Infringement Evidence
		<p>the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> US9738887 (Exhibit 31) at Figs. 1J and 1K:  <ul style="list-style-type: none">
20(d)	amplifying polynucleotides contained with the plurality of samples in the plurality of PCR reaction zones while thermal cycling the PCR reaction zones	<p>The accused workflow comprises amplifying polynucleotides contained with the plurality of samples in the plurality of PCR reaction zones while thermal cycling the PCR reaction zones.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.” 

Claim	Claim Language	Infringement Evidence
		<p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

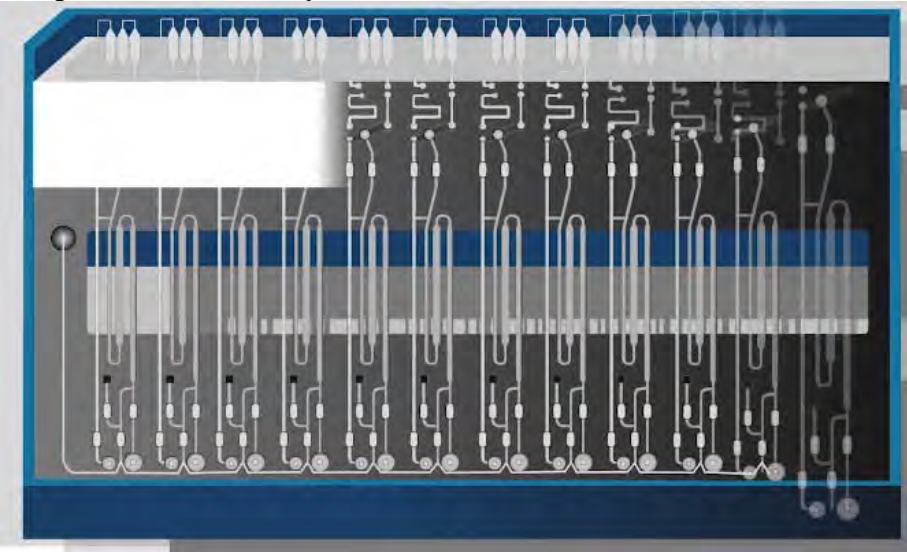
Claim	Claim Language	Infringement Evidence
		<div data-bbox="890 233 1793 776" data-label="Image"> </div> <ul style="list-style-type: none"> <li data-bbox="842 786 1923 1000"> <p>“A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p> <div data-bbox="905 1039 1612 1383" data-label="Image"> </div>

Claim	Claim Language	Infringement Evidence
		<p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module

Claim	Claim Language	Infringement Evidence
		<p>comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip,

Claim	Claim Language	Infringement Evidence
		<p>and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of

Claim	Claim Language	Infringement Evidence
		<p>nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)
20(e)	and maintaining a substantially uniform temperature throughout each PCR reaction zone during each cycle,	The accused workflow comprises amplifying polynucleotides contained with the plurality of samples in the plurality of PCR reaction zones while thermal cycling the PCR reaction zones and maintaining a substantially uniform temperature throughout each PCR reaction zone during each cycle

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		<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 228 1612 574" data-label="Image"> </div> <p data-bbox="793 646 1877 719"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="842 727 1923 1052" style="list-style-type: none"> • “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p data-bbox="793 1092 1110 1125">US9050594 (Exhibit 24)</p> <ul data-bbox="842 1133 1911 1421" style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended


Claim	Claim Language	Infringement Evidence
		<p>configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.

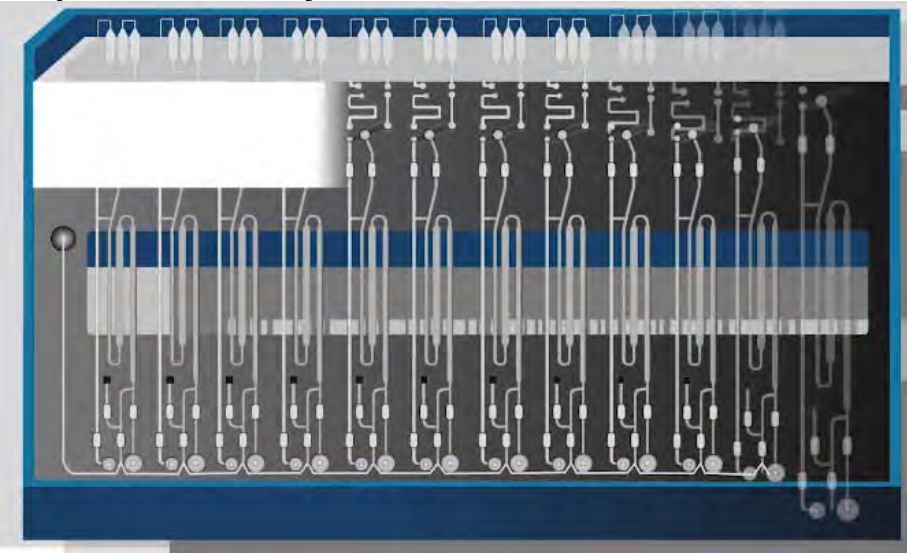
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of

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		<p>the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)</p> <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 2:33-48 “The system 100 functions to enable rapid thermal cycling of samples while providing uniform heating and preventing signal drift. In specific applications, the system 100 can be used to rapidly and controllably thermocycle nucleic acid samples during performance of molecular diagnostic amplification techniques (e.g., PCR, RT-PCR), signal amplification techniques (e.g., bDNA, hybrid capture), and analytical techniques (e.g., gel electrophoresis, mass spectrometry). The system 100 can also provide rapid thermocycling without significant power requirements, ensure a closer correlation between the actual heating temperature and the temperature set-point by implementing an integrated heater-sensor die, and controllably and individually heat small sample volumes (e.g., picoliters, nanoliters) based upon a microfabrication technique that also enables mass production of the system 100.”) U.S. Patent No. 9,499,896 at 2:61-3:3 (“The set of heater-sensor dies 110 functions to controllably heat individual sample volumes. Preferably, each heater sensor die 111 is a thin-film die that can be deposited onto another substrate (e.g., silicon, glass substrate) that can be packaged onto an electronics substrate 140 (e.g., printed circuit board, PCB); however, each heater-sensor die 111 can alternatively comprise any suitable geometry and/or configuration that enables controlled, uniform, and rapid heating of a detection chamber in thermal communication with the heater-sensor die 111.”) U.S. Patent No. 9,499,896 at 3:23-27 (“Preferably, each heater-sensor die 111 in the set of heater sensor dies 110 comprises an assembly including: a first insulating layer 112a that functions to provide an insulating barrier to isolate the heaters and sensors and a heating region 113 that functions to provide uniform sample heating.”)
20(f)	at least one PCR reaction zone separately thermally controllable from another PCR reaction zone.	<p>The accused workflow comprises at least one PCR reaction zone separately thermally controllable from another PCR reaction zone.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/,</p>

Claim	Claim Language	Infringement Evidence
		<p>last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

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		 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of

Claim	Claim Language	Infringement Evidence
		<p>up to eight hours.” <i>Id.</i> at 0:00-0:18</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 228 1612 574" data-label="Image"> </div> <p data-bbox="793 651 1113 683">US9403165 (Exhibit 27)</p> <ul data-bbox="842 691 1921 1421" style="list-style-type: none"> <li data-bbox="842 691 1921 1161">• Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. <li data-bbox="842 1169 1921 1421">• Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the

Claim	Claim Language	Infringement Evidence
		<p>second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module,


Claim	Claim Language	Infringement Evidence
		<p>configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of

Claim	Claim Language	Infringement Evidence
		<p>nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but


Claim	Claim Language	Infringement Evidence
		alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)

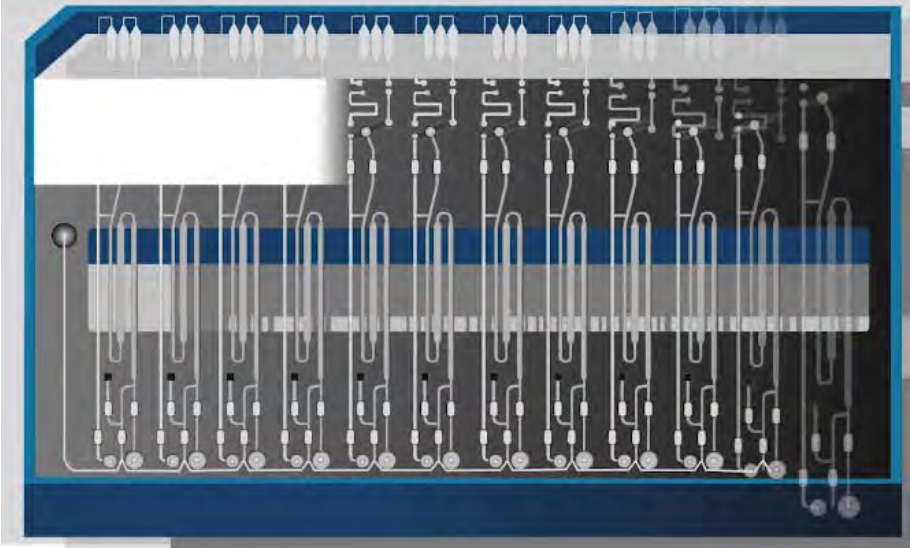
Exhibit 38

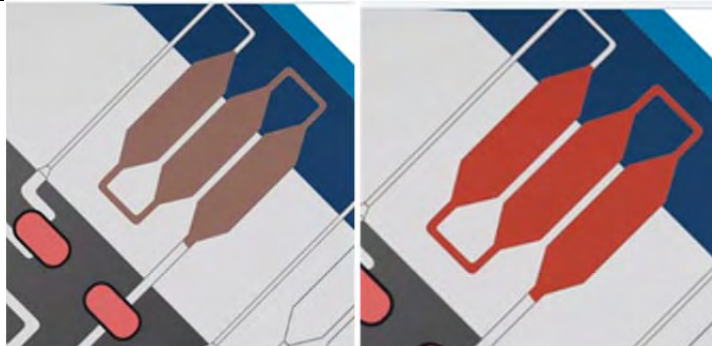
U.S. Patent No. 8,415,103 Infringement Chart

Claim	Claim Language	Infringement Evidence
1(a)	A method of carrying out amplification independently on a plurality of polynucleotide-containing samples, the method comprising:	<p>To the extent the preamble is limiting, the accused workflow includes carrying out amplification independently on a plurality of polynucleotide-containing samples.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p> 

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

Claim	Claim Language	Infringement Evidence
		 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of

Claim	Claim Language	Infringement Evidence
		<p>up to eight hours.” <i>Id.</i> at 0:00-0:18</p> <ul style="list-style-type: none"> <p>“This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59</p>  <p>“A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p>

Claim	Claim Language	Infringement Evidence										
		<div></div> <p>“Patents”, http://www.neumodx.com/patents/, demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 9,539,576; 9,637,775; and 10,093,963 (Exhibit 15)</p> <h2>PATENTS</h2> <table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.</td></tr></table> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none">Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636.	XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.
Product	Patents											
CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.											
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XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.											


Claim	Claim Language	Infringement Evidence
		<p>is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the

Claim	Claim Language	Infringement Evidence
		<p>actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the

Claim	Claim Language	Infringement Evidence
		<p>emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter.</p> <ul style="list-style-type: none"> • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge

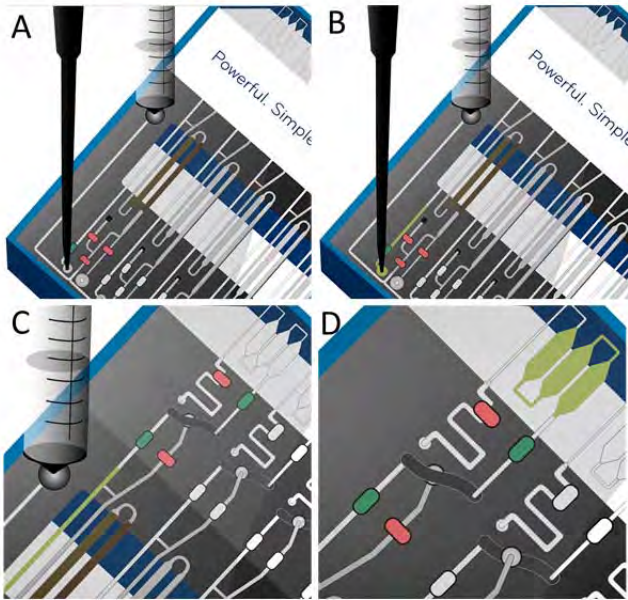
Claim	Claim Language	Infringement Evidence
		<p>210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 10:63-65 ("The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.") • U.S. Patent No. 9,050,594 at 11:56-58 ("The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.") • U.S. Patent No. 9,050,594 at 29:44-47 ("In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample.")
1(b)	introducing the plurality of samples separately into a microfluidic cartridge;	<p>The accused workflow includes introducing the plurality of samples separately into a microfluidic cartridge.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to "VIDEO NeuMoDx™ WORKFLOW" hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • "The liquid handling robot aspirates the PCR-ready solution and transfers it back to the cartridge where it dispenses into the same P-port from which the sample was aspirated." <i>Id.</i> at 3:47-3:57

Claim	Claim Language	Infringement Evidence
		

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 935 1115 967">US9101930 (Exhibit 25)</p> <ul data-bbox="842 976 1923 1408" style="list-style-type: none"> • Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the

Claim	Claim Language	Infringement Evidence
		<p>intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> Claim 11. The cartridge of claim 10, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, wherein the first fluidic pathway is substantially identical to the second fluidic pathway, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second

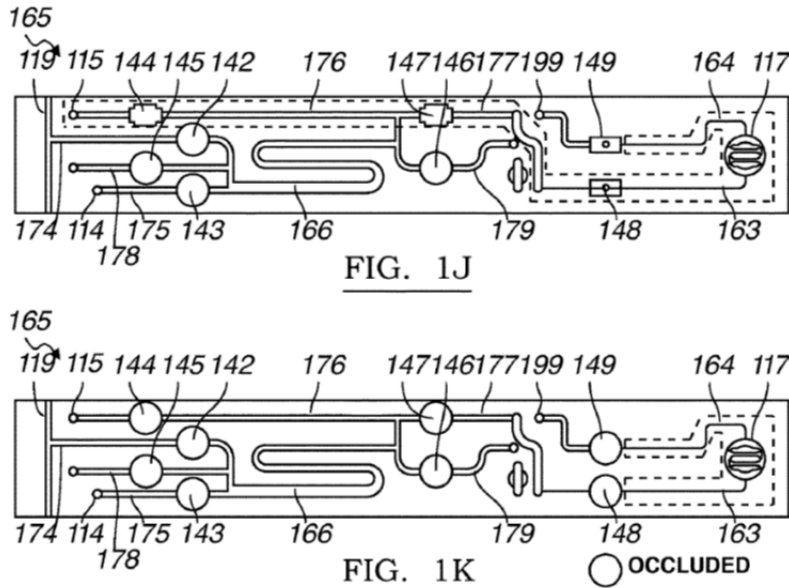
Claim	Claim Language	Infringement Evidence
		<p>sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.


Claim	Claim Language	Infringement Evidence
1(c)	isolating the samples in the microfluidic cartridge;	<p>The accused workflow includes isolating the samples in the microfluidic cartridge.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

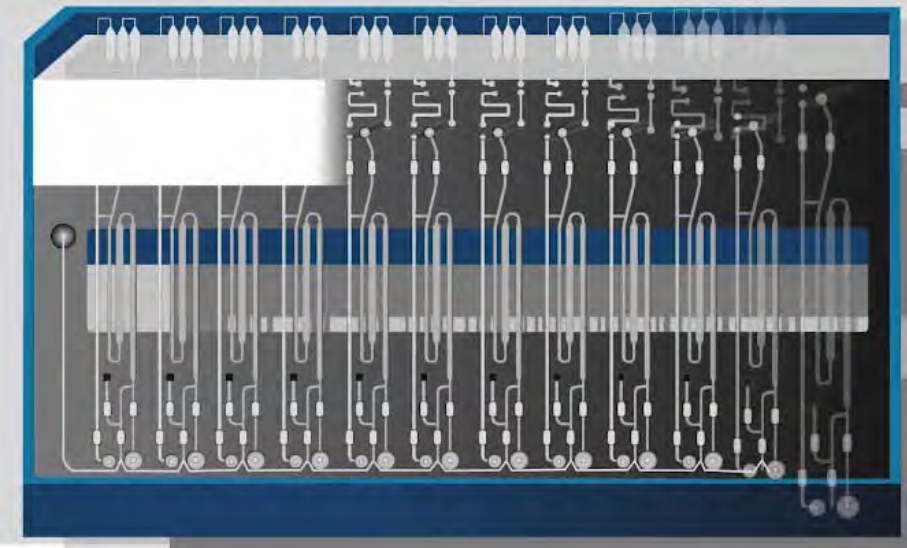
Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 228 1499 532" data-label="Image"> </div> <p data-bbox="793 573 1110 605">US9339812 (Exhibit 26)</p> <ul data-bbox="842 613 1917 1416" style="list-style-type: none"> <li data-bbox="842 613 1917 1344">• Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads. <li data-bbox="842 1344 1917 1416">• Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to

Claim	Claim Language	Infringement Evidence
		<p>facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber.</p> <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined

Claim	Claim Language	Infringement Evidence
		<p>between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured

Claim	Claim Language	Infringement Evidence
		<p>to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at Figs. 1J and 1K:  <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)

Claim	Claim Language	Infringement Evidence
1(d)	placing the microfluidic cartridge in thermal communication with an array of independent heaters; and	<p>The accused workflow includes placing the microfluidic cartridge in thermal communication with an array of independent heaters.</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”  <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.”

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 228 1612 574" data-label="Image"> </div> <p data-bbox="793 651 1115 683">US9050594 (Exhibit 24)</p> <ul data-bbox="842 691 1913 1414" style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment

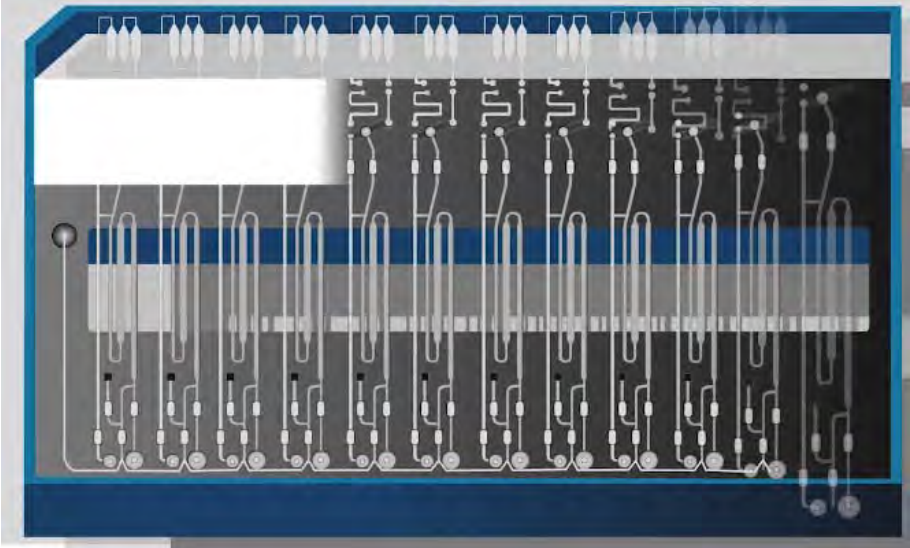
Claim	Claim Language	Infringement Evidence
		<p>configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.</p> <ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater

Claim	Claim Language	Infringement Evidence
		<p>is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection

Claim	Claim Language	Infringement Evidence
		<p>chambers 213 within a microfluidic cartridge 210.”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at 29:44-47 (“In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample.”) <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers. U.S. Patent No. 9,499,896 at 12:15-20 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies 110.”)
1(e)	amplifying polynucleotides in the plurality of samples by	The accused workflow includes amplifying polynucleotides in the plurality of samples by independent application of successive temperature cycles to each sample.

Claim	Claim Language	Infringement Evidence
	independent application of successive temperature cycles to each sample.	<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODx, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

Claim	Claim Language	Infringement Evidence
		<div data-bbox="884 267 1648 738" data-label="Image"> </div> <p data-bbox="800 792 1675 829">40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul data-bbox="842 834 1923 1122" style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p data-bbox="793 1166 1902 1305"><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul data-bbox="842 1312 1923 1414" style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of

Claim	Claim Language	Infringement Evidence
		<p>up to eight hours.” <i>Id.</i> at 0:00-0:18</p> <ul style="list-style-type: none"> <p>“This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59</p>  <p>“A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p>


Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 233 1612 578" data-label="Image"> </div> <p data-bbox="793 651 1113 683">US9403165 (Exhibit 27)</p> <ul data-bbox="842 691 1919 1414" style="list-style-type: none"> <li data-bbox="842 691 1919 1162">• Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. <li data-bbox="842 1170 1919 1414">• Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the

Claim	Claim Language	Infringement Evidence
		<p>second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module,


Claim	Claim Language	Infringement Evidence
		<p>configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of

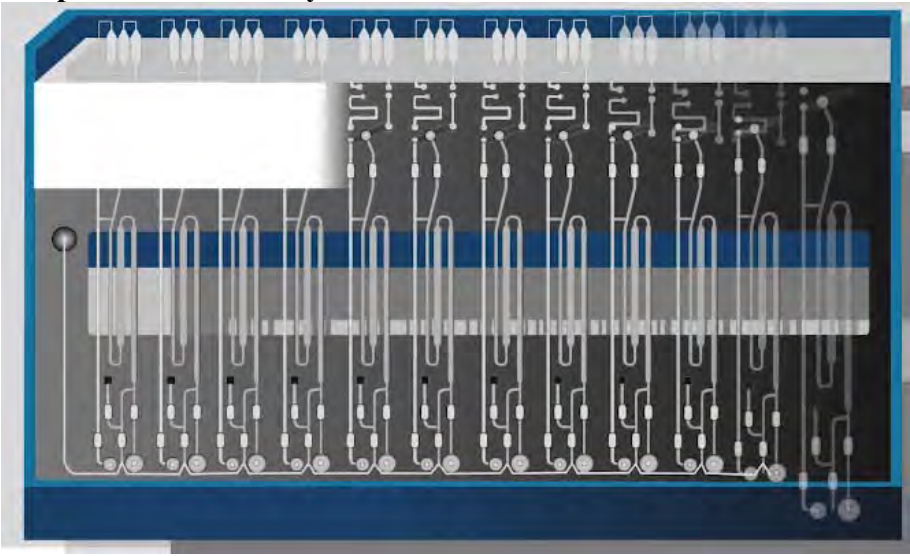
Claim	Claim Language	Infringement Evidence
		<p>nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 29:44-47 (“In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample.”) <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface

Claim	Claim Language	Infringement Evidence
		<p>with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,539,576 at 9:8-12 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies no.”) • U.S. Patent No. 9,539,576 at 12:59-64 (“Upon completion of Block S240, individual heater-sensor dies of the set of heater-sensor dies can be coupled to one or multiple electronics substrates in order to provide uniform heating of

Claim	Claim Language	Infringement Evidence
		individual sample containers with independent control of heating parameters provided at each of the set of heater-sensor dies.”)
15(a)	A method of carrying out amplification independently on a plurality of polynucleotide-containing samples, the method comprising:	<p>To the extent the preamble is limiting, the accused workflow includes carrying out amplification independently on a plurality of polynucleotide-containing samples.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-products/, last visited June 5, 2019 (Exhibit 12)</p> 

Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.” “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent

Claim	Claim Language	Infringement Evidence
		<p>sample processing and real-time PCR.”</p>  <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random


Claim	Claim Language	Infringement Evidence
		<p>access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26


Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 228 1612 574" data-label="Image"> </div> <p data-bbox="793 651 1113 683">US9403165 (Exhibit 27)</p> <ul data-bbox="842 691 1921 1421" style="list-style-type: none"> <li data-bbox="842 691 1921 1161">• Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. <li data-bbox="842 1169 1921 1421">• Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the

Claim	Claim Language	Infringement Evidence
		<p>second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module,

Claim	Claim Language	Infringement Evidence
		<p>configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of

Claim	Claim Language	Infringement Evidence
		<p>nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 29:44-47 (“In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample.”)
15(b)	introducing the plurality of samples in to a microfluidic cartridge,	The accused workflow includes introducing the plurality of samples in to a microfluidic cartridge.


Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The liquid handling robot aspirates the PCR-ready solution and transfers it back to the cartridge where it dispenses into the same P-port from which the sample was aspirated.” <i>Id.</i> at 3:47-3:57 

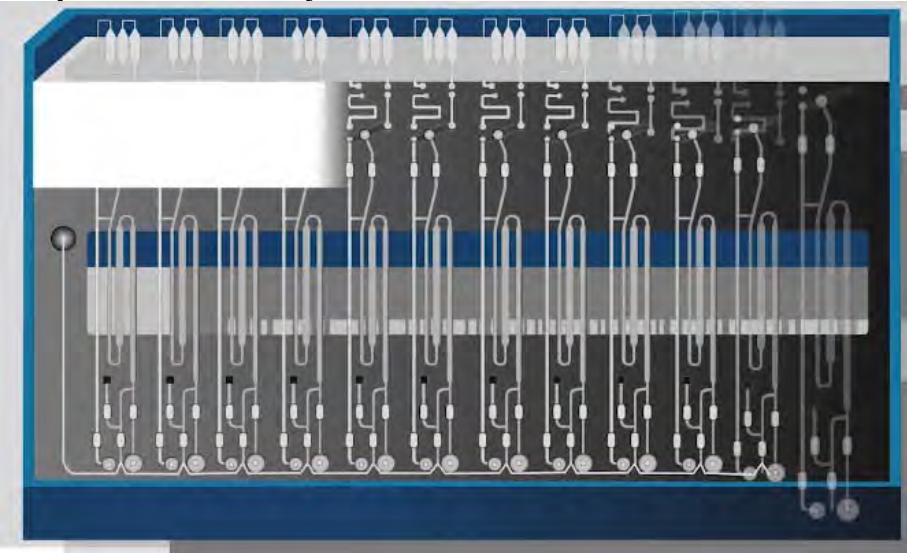
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 935 1115 967">US9101930 (Exhibit 25)</p> <ul data-bbox="842 976 1927 1408" style="list-style-type: none"> • Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the

Claim	Claim Language	Infringement Evidence
		<p>intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate.</p> <ul style="list-style-type: none"> Claim 11. The cartridge of claim 10, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, wherein the first fluidic pathway is substantially identical to the second fluidic pathway, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second

Claim	Claim Language	Infringement Evidence
		<p>sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. •

Claim	Claim Language	Infringement Evidence
15(c)	wherein the cartridge has a plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another;	<p>In the accused workflow, the cartridge has a plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.” • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> • Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

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		 <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of

Claim	Claim Language	Infringement Evidence
		<p>up to eight hours.” <i>Id.</i> at 0:00-0:18</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26

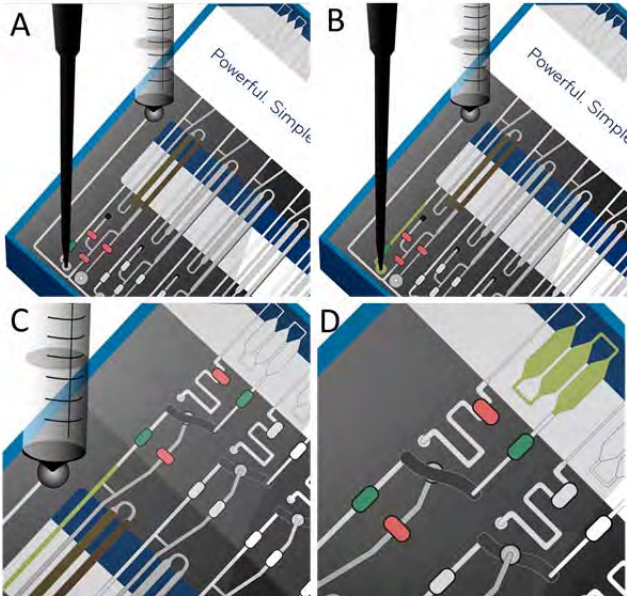
Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 233 1612 574" data-label="Image"> </div> <p data-bbox="793 651 1113 683">US9403165 (Exhibit 27)</p> <ul data-bbox="842 691 1919 1421" style="list-style-type: none"> <li data-bbox="842 691 1919 1161">• Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. <li data-bbox="842 1169 1919 1421">• Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the

Claim	Claim Language	Infringement Evidence
		<p>second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module,

Claim	Claim Language	Infringement Evidence
		<p>configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of

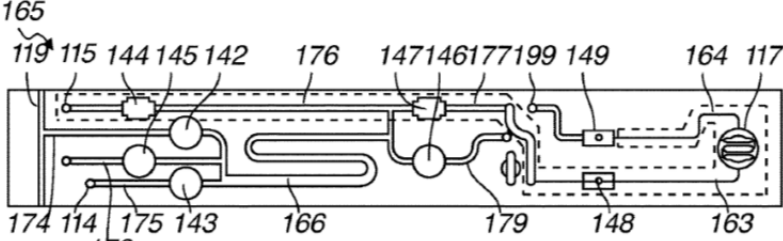
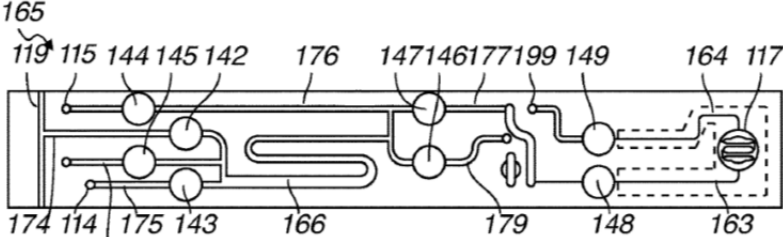
Claim	Claim Language	Infringement Evidence
		<p>nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 29:44-47 (“In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample.”) <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface

Claim	Claim Language	Infringement Evidence
		<p>with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,539,576 at 9:8-12 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies no.”) U.S. Patent No. 9,539,576 at 12:59-64 (“Upon completion of Block S240, individual heater-sensor dies of the set of heater-sensor dies can be coupled to one or multiple electronics substrates in order to provide uniform heating of

Claim	Claim Language	Infringement Evidence
		individual sample containers with independent control of heating parameters provided at each of the set of heater-sensor dies.”)
15(d)	moving the plurality of samples independently of one another into the respective plurality of reaction chambers;	<p>The accused workflow includes moving the plurality of samples independently of one another into the respective plurality of reaction chambers.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 

Claim	Claim Language	Infringement Evidence
		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second

Claim	Claim Language	Infringement Evidence
		<p>branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> • US Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) • US Patent No. 9,738,887 at 15:31-35 (“The segment running to a detection chamber 163 functions to deliver a processed sample fluid to the detection chamber 117 with a reduced quantity of gas bubbles, and the segment running away from the detection chamber 164 functions to deliver a fluid away from the detection chamber 117.”) • US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth

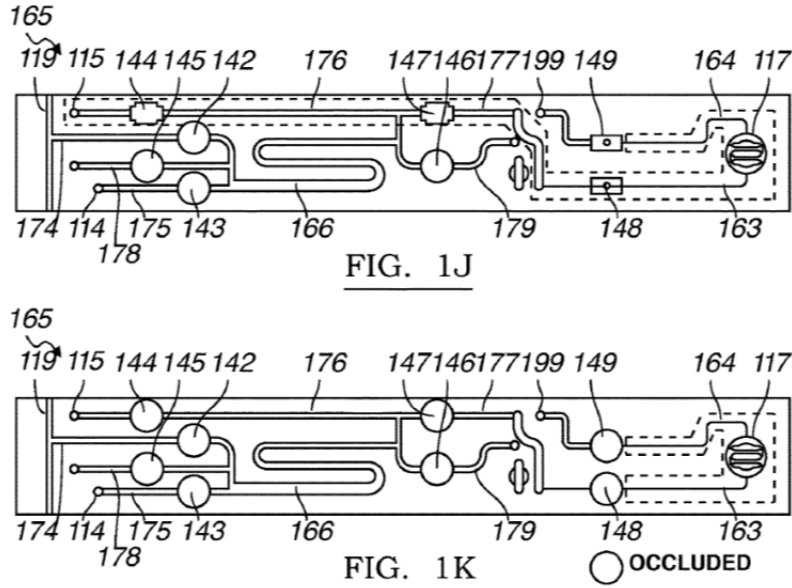
Claim	Claim Language	Infringement Evidence
		<p>truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at Figs. 1J and 1K:  <p style="text-align: center;">FIG. 1J</p>  <p style="text-align: center;">FIG. 1K</p> <p style="text-align: right;">○ OCCLUDED</p>
15(e)	isolating the samples within the plurality of reaction chambers;	<p>The accused workflow includes isolating the samples within the plurality of reaction chambers.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the


Claim	Claim Language	Infringement Evidence
		<p data-bbox="890 235 1822 305">cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08</p>  <p data-bbox="793 1289 1276 1321">US9339812 (Exhibit 26) (Exhibit 26)</p> <ul data-bbox="842 1328 1843 1398" style="list-style-type: none"> • Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions

Claim	Claim Language	Infringement Evidence
		<p>defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads.</p> <ul style="list-style-type: none"> Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber. <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection

Claim	Claim Language	Infringement Evidence
		<p>chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1297 488 1430 521">FIG. 1J</p> <p data-bbox="1297 789 1430 821">FIG. 1K</p> <p data-bbox="1541 789 1709 821">○ OCCLUDED</p> <ul data-bbox="842 854 1892 1219" style="list-style-type: none"> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
15(f)	placing the microfluidic cartridge in thermal communication with an array of independent heaters; and	<p data-bbox="793 1260 1772 1325">The accused workflow includes placing the microfluidic cartridge in thermal communication with an array of independent heaters.</p> <p data-bbox="793 1365 1461 1398"><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”  <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>


Claim	Claim Language	Infringement Evidence
		<div data-bbox="890 228 1793 776" data-label="Image"> </div> <ul style="list-style-type: none"> <li data-bbox="842 784 1921 1000"> <p>“A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p> <div data-bbox="905 1037 1614 1383" data-label="Image"> </div>

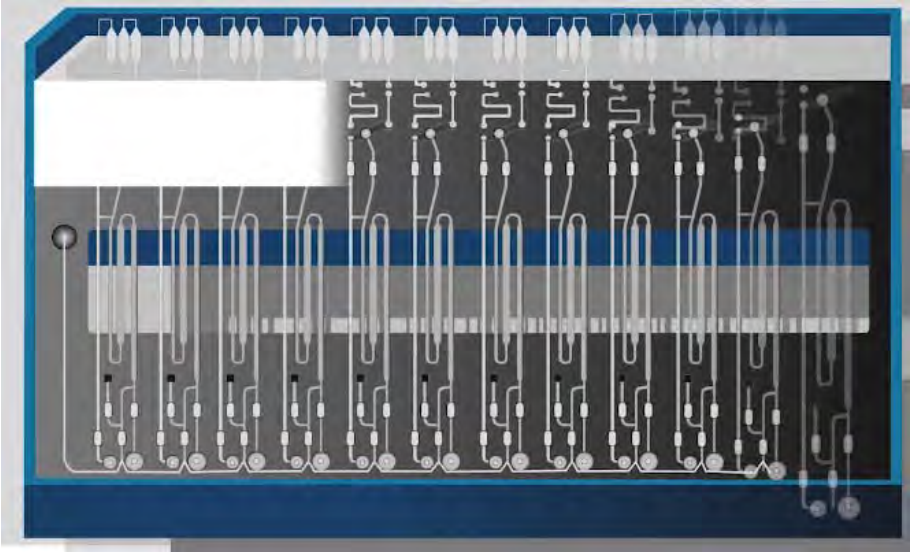
Claim	Claim Language	Infringement Evidence
		<p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic

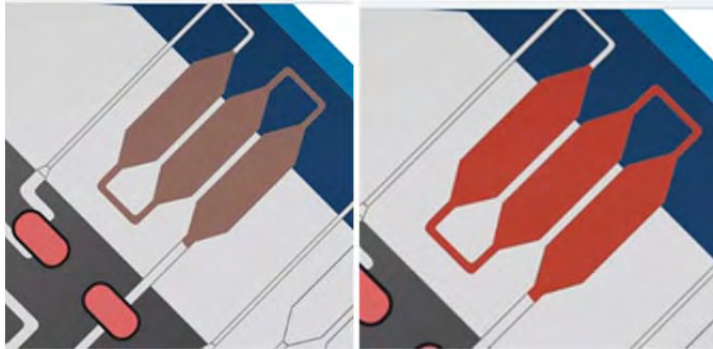
Claim	Claim Language	Infringement Evidence
		<p>acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads,

Claim	Claim Language	Infringement Evidence
		<p>isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 29:44-47 (“In embodiments wherein multiple heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample.”) <p>US9499896 (Exhibit 28)</p> <ul style="list-style-type: none"> • Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising: an assembly including a first insulating layer, a heating region comprising an adhesion material layer coupled to the first

Claim	Claim Language	Infringement Evidence
		<p>insulating layer and a noble material layer coupled to the adhesion material layer, and a second insulating layer coupled to the heating region and to the first insulating layer through a pattern of voids in the heating region, wherein the pattern of voids in the heating region defines a coarse pattern, comprising a global morphology at a first scale and associated with a heating element of the heating region, and a fine pattern, comprising a local morphology at a second scale smaller than the first scale, integrated into the coarse pattern and associated with a sensing element of the heating region; an electronics substrate configured to couple heating elements and sensing elements of the set of heater-sensor dies to a controller; and a set of elastic elements coupled to a second substrate surface of the electronics substrate opposing a first substrate surface of the electronics substrate interfacing with the assemblies of the set of heater-sensor dies and configured to bias each of the set of heater-sensor dies against a detection chamber in a configuration wherein the set of heater-sensor dies is in thermal communication with a set of detection chambers.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,499,896 at 12:15-20 (“Furthermore, the controller 165 can be configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies 110.”)
15(g)	amplifying polynucleotides contained within the plurality of samples, by application of successive temperature cycles independently to the reaction chambers.	<p>The accused workflow includes amplifying polynucleotides contained within the plurality of samples, by application of successive temperature cycles independently to the reaction chambers.</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result” platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieveing [sic] optimal operational and clinical performance for our customers and their patients.”

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”  <p><i>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</i></p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a

Claim	Claim Language	Infringement Evidence
		<p>combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.”</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “The NeuMoDx Molecular N96 and N288 are fully automated sample to result molecular diagnostics platforms. They provide continuous random access processing with initial results in one hour and operator walk away time of up to eight hours.” <i>Id.</i> at 0:00-0:18 • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the

Claim	Claim Language	Infringement Evidence
		<p>cartridge into three thin PCR chambers and the amplification process begins. During a series of independent heat on-heat off sequences, an optical scanner measures the level of fluorescence emitted, and converts it into the qualitative or quantitative results which are displayed as amplification curves for analysis by the laboratorian.” <i>Id.</i> at 3:58-4:26</p>  <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> • Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. • Claim 10. The cartridge of claim 8, wherein the first layer is a unitary

Claim	Claim Language	Infringement Evidence
		<p>construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> • Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample. • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer.

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module. • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent

Claim	Claim Language	Infringement Evidence
		<p>mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”) U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) U.S. Patent No. 9,050,594 at 29:44-47 (“In embodiments wherein multiple

Claim	Claim Language	Infringement Evidence
		<p>heaters are provided, each heater is preferably independent to allow independent control of heating time and temperature for each sample.”)</p> <p>US9539576 (Exhibit 29)</p> <ul style="list-style-type: none"> Claim 1. A system for thermocycling biological samples within detection chambers comprising: a set of heater-sensor dies, each heater-sensor die in the set of heater-sensor dies comprising a heating surface configured to interface with a detection chamber and an inferior surface, inferior to the heating surface, including a connection point, wherein each of the set of heater-sensor dies includes a heating element and a sensing element; an electronics substrate, comprising a first substrate surface coupled to the inferior surface of each of the set of heater-sensor dies, a set of apertures longitudinally spaced across the electronics substrate and providing access through the electronics substrate to the set of heater-sensor dies, and a second substrate surface inferior to the first substrate surface, wherein the electronics substrate comprises a set of substrate connection points at least at one of the first substrate surface, an aperture surface defined within at least one of the set of apertures, and the second substrate surface, and wherein the electronics substrate couples the heating element and the sensing element of each of the set of heater-sensor dies to a controller; a set of heat-sink supports coupled to at least one of 1) the set of heater-sensor dies, through the set of apertures, and 2) the second substrate surface of the electronics substrate and configured to dissipate heat generated by the set of heater-sensor dies, wherein at least one of the set of heat-sink supports includes an integrated cooling element, and wherein a base surface of each of the set of heat-sink supports is coupled to an elastic element that transmits a biasing force through the electronics substrate, thereby maintaining thermal communication between the set of heater-sensor dies and a set of detection chambers upon alignment of the set of heater-sensor dies with the set of detection chambers; and a set of wire bonds, including a wire bond coupled between the connection point of at least one of the set of heater-sensor dies and one of the set of substrate connection points. U.S. Patent No. 9,539,576 at 9:8-12 (“Furthermore, the controller 165 can be

Claim	Claim Language	Infringement Evidence
		<p>configured to control individual heater-sensor dies 111 in order to provide unique heating parameters for individual detection chambers and/or can be configured to provide common heating parameters for all heater-sensor dies 111 in the set of heater-sensor dies no.")</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,539,576 at 12:59-64 ("Upon completion of Block S240, individual heater-sensor dies of the set of heater-sensor dies can be coupled to one or multiple electronics substrates in order to provide uniform heating of individual sample containers with independent control of heating parameters provided at each of the set of heater-sensor dies.")

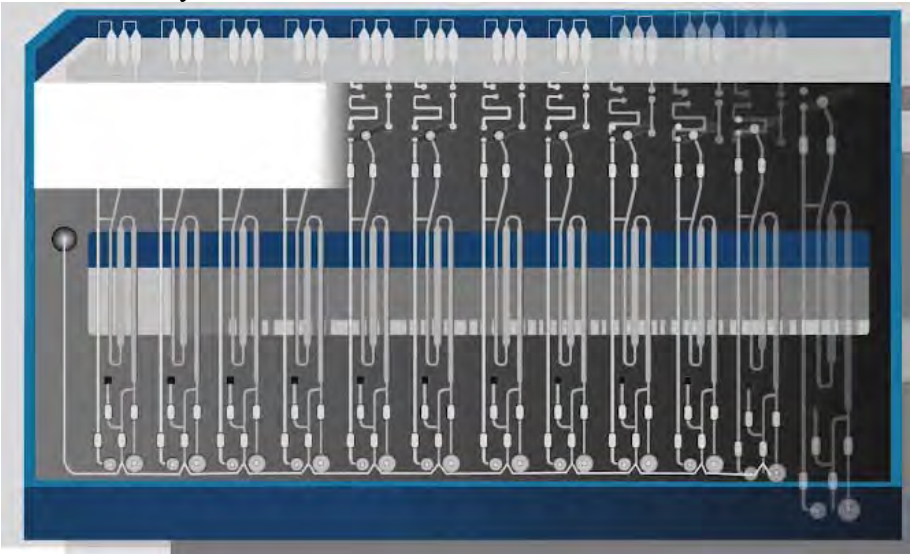
EXHIBIT 39

U.S. Patent No. 8,709,787 Infringement Chart

Claim	Claim Language	Infringement Evidence
10(a)	A microfluidic substrate, comprising:	<p>To the extent the preamble is limiting, the accused product is a microfluidic substrate.</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.” <div data-bbox="884 623 1638 1091" data-label="Image"> </div> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample

Claim	Claim Language	Infringement Evidence
		<p>microfluidic cartridge.”</p> <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” • “The NeuMoDx™ 96 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 96 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” • “The NeuMoDx™ 288 Molecular System is designed for the automated extraction and isolation of nucleic acids, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR. The NeuMoDx™ 288 Molecular System consists of the instrument with touchscreen computer, accessories, and reagents and consumables.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/product/neumodx-288/, last visited June 3, 2019 (Exhibit 13)</p> <ul style="list-style-type: none"> • “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/product/neumodx-96/, last visited June 3, 2019 (Exhibit 14)</p>


Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> “FEATURES AND BENEFITS... Fluorescence detection at five wavelengths enabling multiplexed amplification reactions... Real-time detection of products of amplification.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>0600101_Rev-D-IFU-NeuMoDx-RELEASE-Solution-US-ONLY-FINAL-25Oct2018.pdf (Exhibit 20)</p> <ul style="list-style-type: none"> “NeuMoDx™ RELEASE Solution INSTRUCTIONS FOR USE... The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) and the dried Master Mix contained in a NeuMoDx test strip. The System then dispenses the prepared RT-PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.” <p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO </p>

Claim	Claim Language	Infringement Evidence
		<p>NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 <p>“Patents”, http://www.neumodx.com/patents/, demonstrating that NeuMoDx marks its products with US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; 9,452,430; 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; 10,010,888; 9,382,532; 9,540,636; 9,499,896; 9,539,576; 9,637,775; and 10,093,963. (Exhibit 15)</p>

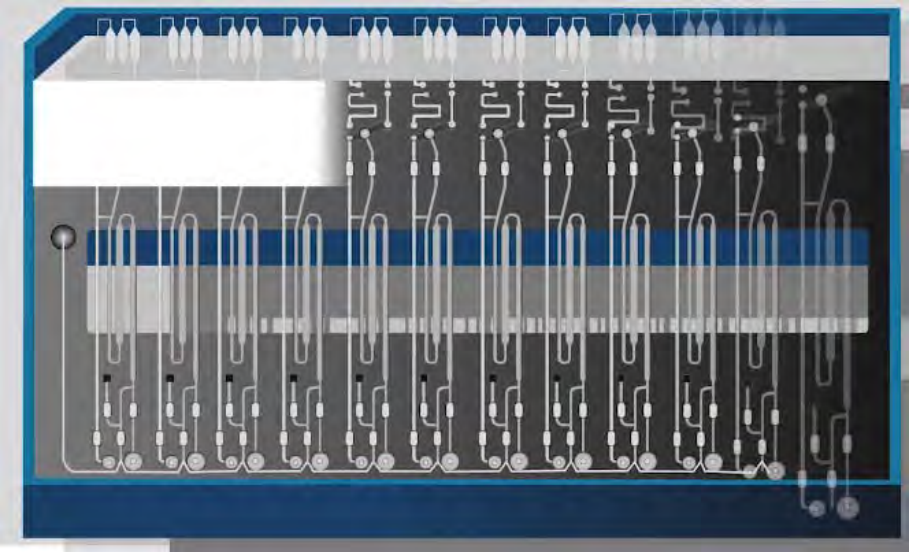
Claim	Claim Language	Infringement Evidence										
		<div><div>PATENTS</div><table><tr><th>Product</th><th>Patents</th></tr><tr><td>CARTRIDGE</td><td>US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.</td></tr><tr><td>P02 (overall system and method)</td><td>US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.</td></tr><tr><td>EXTRACTION PLATE</td><td>US Patent Nos. 9,382,532; and 9,540,636.</td></tr><tr><td>XPCR MODULE</td><td>US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.</td></tr></table></div> <div>US9738887 (Exhibit 31)<ul style="list-style-type: none">Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent port, the fluid port, and the detection chamber.Claim 11. The cartridge of claim 1, wherein the detection chamber comprises a first, a second, and a third detection chamber segment wherein each of the first, the second, and the third detection chamber segment is a broad chamber of which a projection onto a plane is substantially rectangular, wherein a first end of the second detection chamber segment is connected to the first detection chamber segment by a first narrow fluidic channel, and wherein a second end of the second detection chamber segment is connected to the third detection</div>	Product	Patents	CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.	P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.	EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636.	XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.
Product	Patents											
CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.											
P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.											
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XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.											

Claim	Claim Language	Infringement Evidence
		<p>chamber segment by a second narrow fluidic channel.</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at FIG. 1A: <p>FIG. 1A</p> U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste

Claim	Claim Language	Infringement Evidence
		<p>chamber, and to pass through the vent region.”)</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 2:36-3:5. (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140... In a specific application, the microfluidic cartridge 100 can be used to facilitate a PCR procedure for analysis of a sample containing nucleic acids.”) US Patent No. 9,738,887 at 13:7-18. (“The top layer 110 of an embodiment of the microfluidic cartridge 100 functions to accommodate elements involved in performing a molecular diagnostic procedure (e.g. PCR), such that a sample containing nucleic acids, passing through the cartridge, can be manipulated by the elements involved in performing the molecular diagnostic procedure. The top layer 110 is preferably composed of a structurally rigid/stiff material with low autofluorescence, such that the top layer 110 does not interfere with sample detection by fluorescence or chemiluminescence techniques, and an appropriate glass transition temperature and chemical compatibility for PCR or other amplification techniques.”) US Patent No. 9,738,887 at 13:35-42. (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) US Patent No. 9,738,887 at 15:29-39 (“The segments may be arranged in at

Claim	Claim Language	Infringement Evidence
		<p>least one of several configurations to facilitate isolation, processing, and amplification of a nucleic acid sample ...").</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 23:20-24 ("The top layer 110 of the specific embodiment of the microfluidic cartridge 100 functions preferably as described in Section 1.1, and is composed of polypropylene with low autofluorescence and a glass transition temperature suitable for PCR.")
10(b)	a plurality of sample lanes,	<p>The accused microfluidic substrate comprises a plurality of sample lanes,</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf</i> (Exhibit 18)</p> <ul style="list-style-type: none"> Describing "...microfluidic cartridges capable of performing independent sample processing and real-time PCR."  <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul style="list-style-type: none"> "NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, "sample to result"

Claim	Claim Language	Infringement Evidence
		<p>platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.”</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. <p><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul style="list-style-type: none"> • “NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time polymerase chain reaction (PCR) chemistry in a multi-sample microfluidic cartridge.” <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System.... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.”

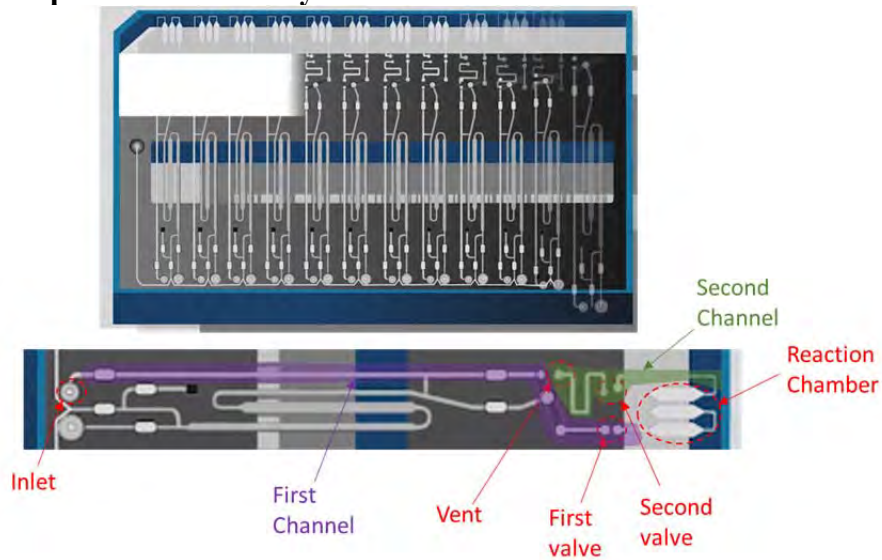
Claim	Claim Language	Infringement Evidence
		<p>K173725.pdf (Exhibit 23)</p> <ul style="list-style-type: none"> “510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY AND INSTRUMENT COMBINATION TEMPLATE... Test Principle... After reconstitution of the dried PCR reagents, the NeuMoDx System dispenses the prepared PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Amplification and detection of the control and target DNA sequences occur in PCR chamber.” <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the


Claim	Claim Language	Infringement Evidence
		<p>cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08</p> <p>US9403165 (Exhibit 27)</p> <ul style="list-style-type: none"> Claim 8. A cartridge for processing a sample, the cartridge comprising: a first layer and an intermediate substrate coupled to the first layer and partially separated from the first layer by a film layer, wherein the intermediate substrate is configured to form a sealed waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids external to the waste chamber; and a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway and formed by at least a portion of the second fluidic pathway, wherein the first fluidic pathway and the second fluidic pathway are each at least partially separated from the corrugated surface by an elastomeric layer, and each fluidic pathway is configured to transfer waste fluid of the sample into the waste chamber through a set of openings of the intermediate substrate. Claim 10. The cartridge of claim 8, wherein the first layer is a unitary construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port. <p>US9050594 (Exhibit 24)</p> <ul style="list-style-type: none"> Claim 1: A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well configured to facilitate a combination of a set of magnetic beads with a biological sample, thus producing a magnetic bead-sample; and a molecular diagnostic module, configured to process at

Claim	Claim Language	Infringement Evidence
		<p>least one magnetic bead-sample obtained from the capture plate, and separate nucleic acids from magnetic beads, wherein the molecular diagnostic module comprises: a cartridge platform comprising a magnet receiving slot, an actuator configured to displace the cartridge platform, a magnet, wherein an extended configuration of the actuator allows the magnet to pass through the magnet receiving slot to facilitate separation of the at least one nucleic acid volume, and a cam card contacting a set of pins, wherein the extended configuration of the actuator combined with movement of the cam card displaces a subset of the set of pins through a set of slots of the cartridge platform, to define at least one distinct pathway configured to receive at least one magnetic bead-sample.</p> <ul style="list-style-type: none"> • Claim 13. The system of claim 1, wherein the molecular diagnostic module is configured receive and align a microfluidic cartridge comprising a set of sample port-reagent port pairs, a fluid port, a set of detection chambers, a waste chamber, an elastomeric layer, and a set of fluidic pathways, wherein each fluidic pathway of the set of fluidic pathways is coupled to a sample port-reagent port pair, the fluid port, and a detection chamber, comprises a segment configured to cross the magnet, and is configured to transfer a waste fluid to the waste chamber, and to be occluded upon deformation of the elastomeric layer. • Claim 16. A system for processing and detecting nucleic acids, comprising: a capture plate comprising at least one well containing a set of magnetic beads configured to be combined with a biological sample to produce a magnetic bead-sample; an assay strip comprising at least one well containing a molecular diagnostic reagent configured to be combined with a nucleic acid volume to produce a nucleic acid-reagent mixture; a molecular diagnostic module, configured to process the magnetic bead-sample from the capture plate, separate the nucleic acid volume from the magnetic bead-sample, and analyze the nucleic acid-reagent mixture from the assay strip, wherein the molecular diagnostic module comprises a cartridge platform including a set of parallel slots, a cam card, and a set of pins contacting the cam card, wherein movement of the cam card displaces a subset of the set of pins through a subset of the set of parallel slots to define at least one pathway configured to receive the magnetic bead-sample; and a liquid handling system configured to transfer the magnetic bead-

Claim	Claim Language	Infringement Evidence
		<p>sample from the capture plate to the molecular diagnostic module, transfer the nucleic acid volume from the molecular diagnostic module to the assay strip, and transfer the nucleic acid-reagent mixture from the assay strip to the molecular diagnostic module.</p> <ul style="list-style-type: none"> • Claim 18. The system of claim 16, wherein the molecular diagnostic module comprises an optical subsystem comprising at least one unit, wherein each unit includes an excitation filter, an emission filter, a photodetector aligned with the emission filter, and a dichroic mirror configured to reflect light from the excitation filter toward the nucleic acid-reagent mixture, and to transmit light from the nucleic acid reagent mixture, through the emission filter, and toward the photodetector wherein each unit of the optical subsystem further comprises an LED aligned with the excitation filter, wherein the LED provides multiple wavelengths of light corresponding to at least one of the excitation filter, the dichroic mirror, and the emission filter. • Claim 19. The system of claim 16, wherein the molecular diagnostic module further comprises a heater and a detection chamber heater, wherein the heater is configured to heat the magnetic bead-sample, and wherein the detection chamber heater is configured to individually heat the nucleic acid-reagent mixture, and wherein at least one of the heater and the detection chamber heater is a Peltier heater. • U.S. Patent No. 9,050,594 at Abstract (“A system and method for processing and detecting nucleic acids from a set of biological samples, comprising: a capture plate and a capture plate module configured to facilitate binding of nucleic acids within the set of biological samples to magnetic beads; a molecular diagnostic module configured to receive nucleic acids bound to magnetic beads, isolate nucleic acids, and analyze nucleic acids, comprising a cartridge receiving module, a heating/cooling subsystem and a magnet configured to facilitate isolation of nucleic acids, a valve actuation subsystem configured to control fluid flow through a microfluidic cartridge for processing nucleic acids, and an optical subsystem for analysis of nucleic acids; a fluid handling system configured to deliver samples and reagents to components of the system to

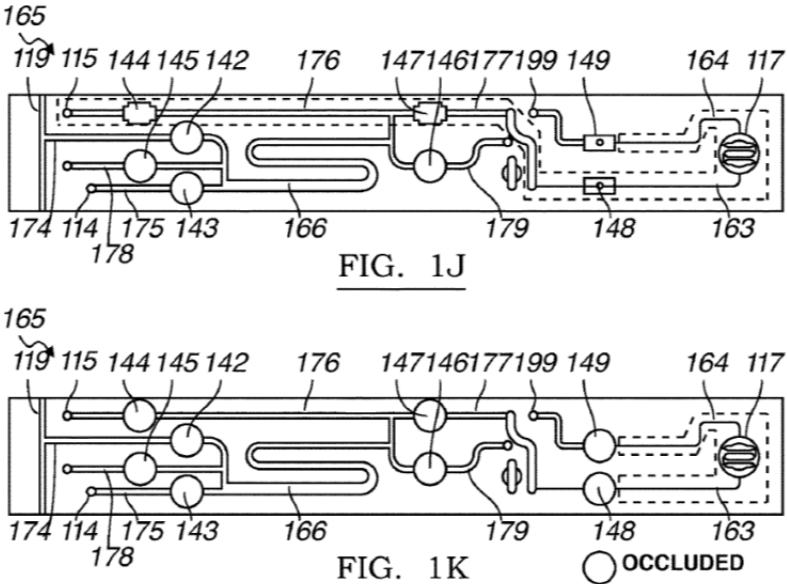
Claim	Claim Language	Infringement Evidence
		<p>facilitate molecular diagnostic protocols; and an assay strip configured to combine nucleic acid samples with molecular diagnostic reagents for analysis of nucleic acids.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,050,594 at 9:4-21 (“The linear actuator 146 further functions to move a nozzle 149 coupled to the liquid handling system 250, in order to couple the liquid handling system 250 to a fluid port 222 of the microfluidic cartridge 210... The vertical displacement also allows the microfluidic cartridge 210 to receive a magnet 160, which provides a magnetic field to facilitate a subset of a molecular diagnostic protocol, and detection chamber heaters 157, which allows amplification of nucleic acids for molecular diagnostic protocols requiring heating and cooling of the nucleic acid (e.g. PCR).”) • U.S. Patent No. 9,050,594 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”) • U.S. Patent No. 9,050,594 at 11:56-58 (“The set of detection chamber heaters 157 functions to individually heat detection chambers of a set of detection chambers 213 within a microfluidic cartridge 210.”) • U.S. Patent No. 9,050,594 at 31:32043 (“Step S460 recites transferring each of the set of nucleic acid-reagent mixtures, through the corresponding fluidic pathway of the set of fluidic pathways, to a detection chamber of a set of detection chambers, which functions to deliver the set of nucleic acid-reagent mixtures to an isolated detection chamber for further processing and analysis. Preferably, all nucleic acid-reagent mixtures in the set of nucleic acid-reagent mixtures are transferred simultaneously to the set of fluidic pathways, but alternatively, each nucleic acid-reagent mixture in the set of nucleic acid reagent mixtures may be transferred to a corresponding fluidic pathway independently of the other nucleic acid reagent mixtures.”)
10(c)	wherein each of the plurality of sample lanes comprises a microfluidic network having, in	In the accused microfluidic substrate, each of the plurality of sample lanes comprises a microfluidic network having, in fluid communication with one another, an inlet.

Claim	Claim Language	Infringement Evidence
	fluid communication with one another: an inlet;	<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> “The liquid handling robot aspirates the PCR-ready solution and transfers it back to the cartridge where it dispenses into the same P-port from which the sample was aspirated.” <i>Id.</i> at 3:47-3:57

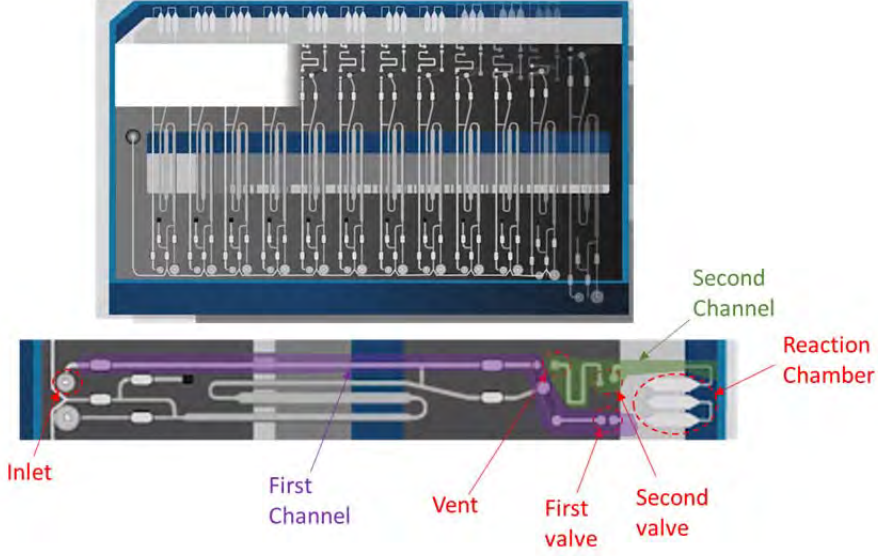
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

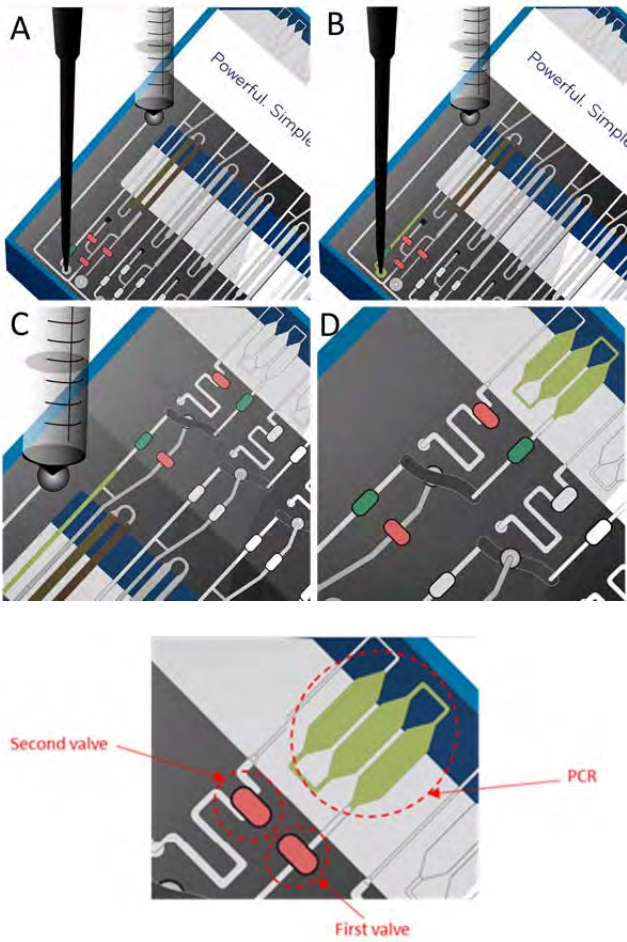
Claim	Claim Language	Infringement Evidence
		<div data-bbox="905 240 1528 837"> </div> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.”) U.S. Patent No. 9,738,887 at 15:31-35 (“The segment running to a detection chamber 163 functions to deliver a processed sample fluid to the detection chamber 117 with a reduced quantity of gas bubbles, and the segment running away from the detection chamber 164 functions to deliver a fluid away from the detection chamber 117.”) U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142,

Claim	Claim Language	Infringement Evidence
		<p>144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p>
10(d)	a first valve and a second valve;	<p>In the accused microfluidic substrate, each of the plurality of sample lanes comprises a microfluidic network having, in fluid communication with one another, a first valve and a second valve.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

Claim	Claim Language	Infringement Evidence
		<div data-bbox="890 233 1793 776" data-label="Image"> </div> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08 (see below, with elements of the accused product marked for reference)

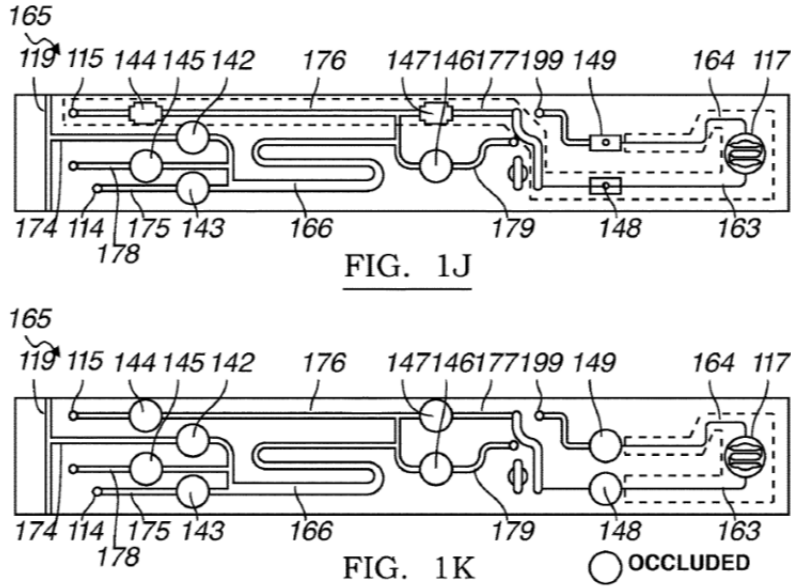
Claim	Claim Language	Infringement Evidence
		 <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

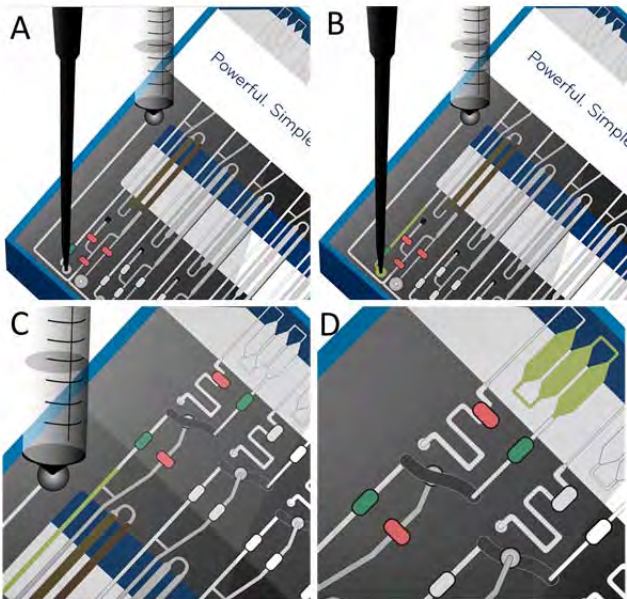
Claim	Claim Language	Infringement Evidence
		 <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module,

Claim	Claim Language	Infringement Evidence
		<p>the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads.</p> <ul style="list-style-type: none"> • Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber. <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve

Claim	Claim Language	Infringement Evidence
		<p>guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p>

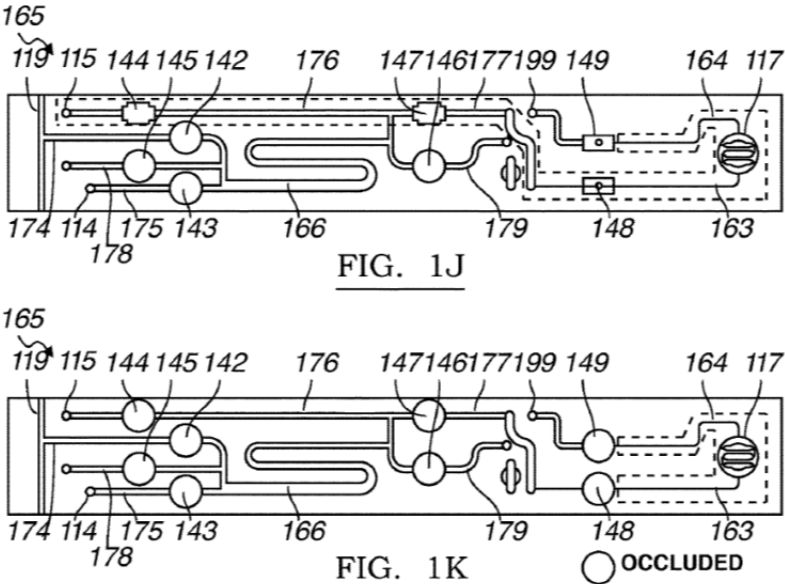
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”)at Figs. 1J and 1K:

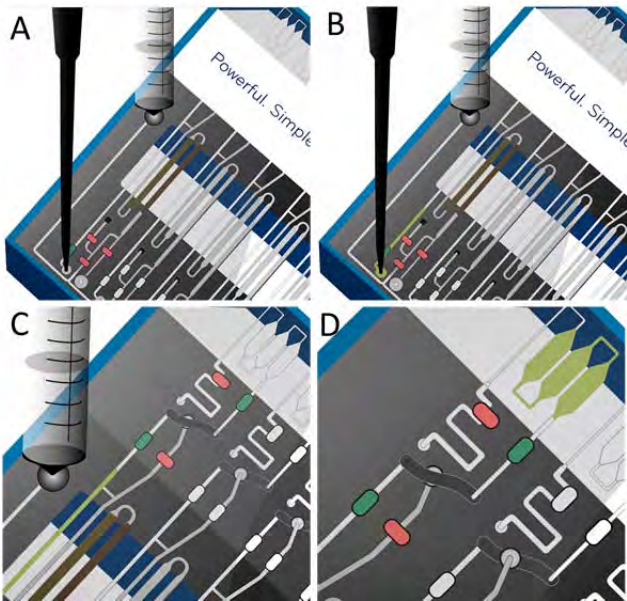
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1297 488 1430 521">FIG. 1J</p> <p data-bbox="1297 789 1430 821">FIG. 1K</p> <p data-bbox="1541 789 1709 821">○ OCCLUDED</p> <ul style="list-style-type: none"> <li data-bbox="842 854 1892 1211">US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
10(e)	a first channel leading from the inlet, via the first valve, to a reaction chamber; and	The accused microfluidic substrate comprises a first channel leading from the inlet, via the first valve, to a reaction chamber.

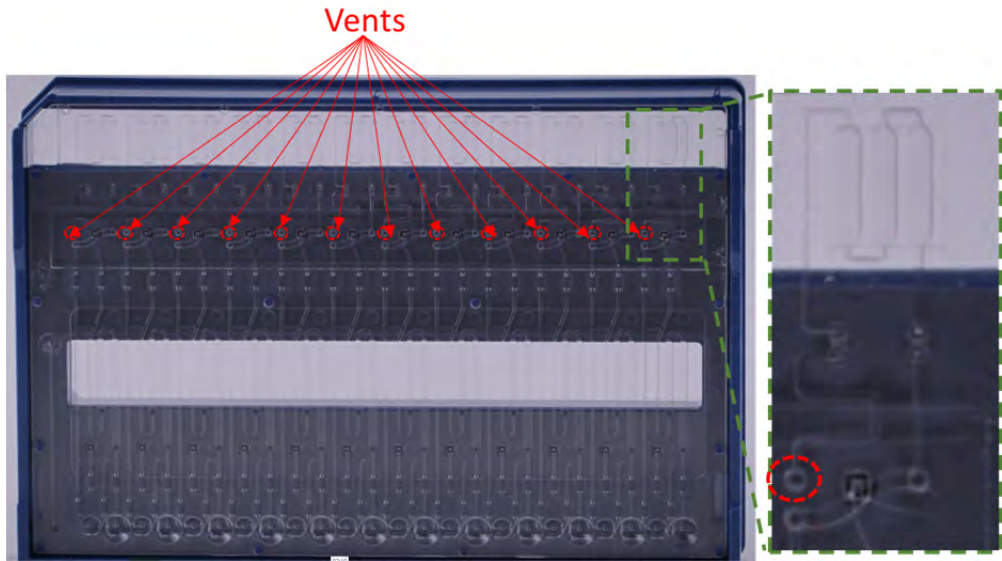
Claim	Claim Language	Infringement Evidence
		<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODx (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. <u>(Exhibit 16)</u></p> <ul style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08  <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction

Claim	Claim Language	Infringement Evidence
		<p>perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 13:35-42 (“The set of fluidic pathways 160 of the microfluidic cartridge 100 functions to provide a fluid network into which volumes of sample fluids, reagents, buffers and/or gases used in a molecular diagnostics protocol may be delivered, out of which waste fluids may be

Claim	Claim Language	Infringement Evidence
		<p>eliminated, and by which processed nucleic acid samples may be delivered to a detection chamber for analysis, which may include amplification and/or detection.")</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 15:31-35 ("The segment running to a detection chamber 163 functions to deliver a processed sample fluid to the detection chamber 117 with a reduced quantity of gas bubbles, and the segment running away from the detection chamber 164 functions to deliver a fluid away from the detection chamber 117.") US Patent No. 9,738,887 at 17:27-49 ("Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.") US Patent No. 9,738,887 at Figs. 1J and 1K:

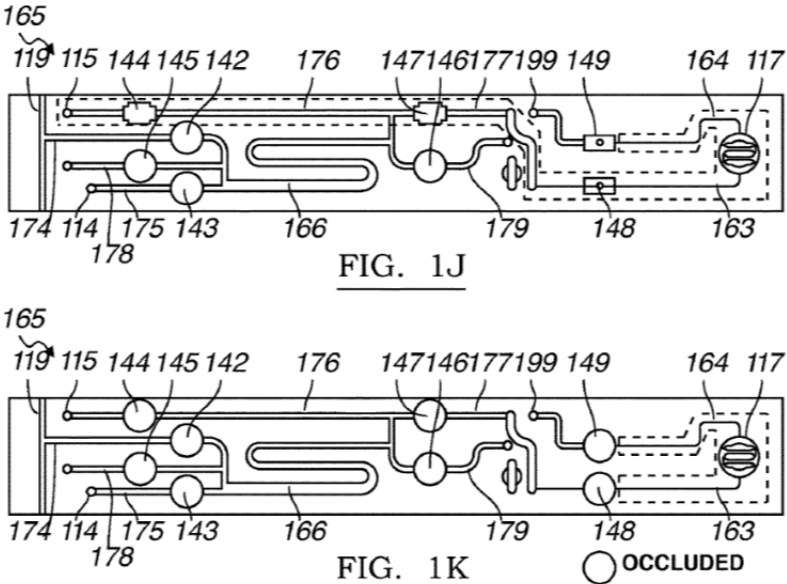
Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p>
10(f)	a second channel leading from the reaction chamber, via the second valve, to a vent,	<p>In the accused microfluidic substrate, each of the plurality of sample lanes comprises a microfluidic network having, in fluid communication with one another, a second channel leading from the reaction chamber, via the second valve, to a vent.</p> <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p>

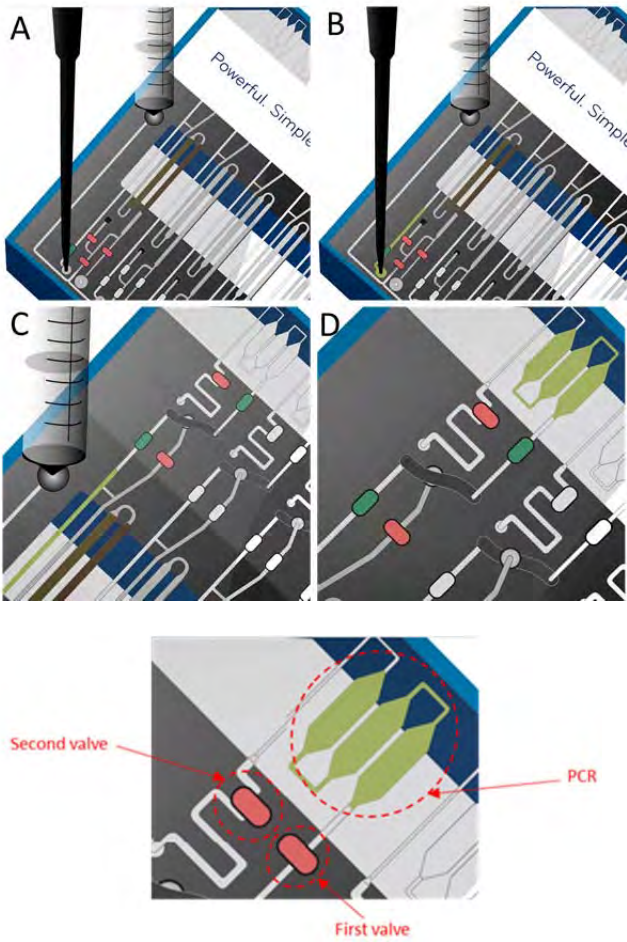
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="842 873 1877 1019">On information and belief, in the accused microfluidic substrate, each of the plurality of sample lanes comprises a microfluidic network having, in fluid communication with one another, . . . a second channel leading from the reaction chamber, via the second valve, to a vent.</p> <ul data-bbox="842 1024 1020 1057" style="list-style-type: none"> • <i>Id.</i> at 2:10

Claim	Claim Language	Infringement Evidence
		 <p>The image shows a cartridge assembly with a top cover and a base. Red arrows point from the word 'Vents' to a row of small circular openings on the top cover. A dashed green box highlights a section on the right side of the cartridge, which includes a larger circular opening at the bottom, also circled in red.</p> <p>US9101930 (Exhibit 25)</p> <ul style="list-style-type: none"> Claim 10. A cartridge, configured to facilitate processing and detecting of nucleic acids, comprising: a first layer and an intermediate substrate, coupled to the first layer, wherein the intermediate substrate defines a waste chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of parallel voids spanning a majority of a width of the intermediate substrate and external to the waste chamber, wherein the set of voids is accessible from a direction perpendicular to a broad surface of the first layer; a first fluidic pathway, formed by at least a portion of the first layer; and a second fluidic pathway in parallel with the first fluidic pathway, formed by at least a portion of the first layer, wherein the first fluidic pathway and the second fluidic pathway are each superior to the intermediate substrate, are each at least partially separated from the corrugated surface of the intermediate substrate by an elastomeric layer and are each configured to transfer waste to the waste chamber through a set of openings of the intermediate substrate. Claim 11. The cartridge of claim 10, wherein the first layer is a unitary

Claim	Claim Language	Infringement Evidence
		<p>construction comprising a first sample port-reagent port pair including a first sample port, a second sample port-reagent port pair including a second sample port, a fluid port, a first detection chamber, and a second detection chamber, wherein the first fluidic pathway is coupled to the first sample port-reagent port pair and the first detection chamber, wherein the second fluidic pathway is coupled to the second sample port-reagent port pair and the second detection chamber, wherein the first fluidic pathway is substantially identical to the second fluidic pathway, and wherein at least one of the first fluidic pathway and the second fluidic pathway is coupled to the fluid port.</p> <ul style="list-style-type: none"> • Claim 13. The cartridge of claim 11, further comprising a heating region as a recessed region of the first layer that is parallel to the set of parallel voids of the corrugated surface, and a vent region, such that the first fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the first detection chamber, and the second fluidic pathway is configured to cross the heating region and to pass through the vent region upstream of the second detection chamber. • Claim 15. The cartridge of claim 13, wherein at least of the first fluidic pathway and the second fluidic pathway is coupled to an end vent configured to provide fine metering of fluid flow. <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent

Claim	Claim Language	Infringement Evidence
		<p>port, the fluid port, and the detection chamber.</p> <ul style="list-style-type: none"> • Claim 10. The cartridge of claim 1, wherein a terminal portion of the fluidic pathway is coupled to an end vent, configured to provide fine metering of fluid flow. • U.S. Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) • U.S. Patent No. 9,738,887 at Figs. 1J and 1K:

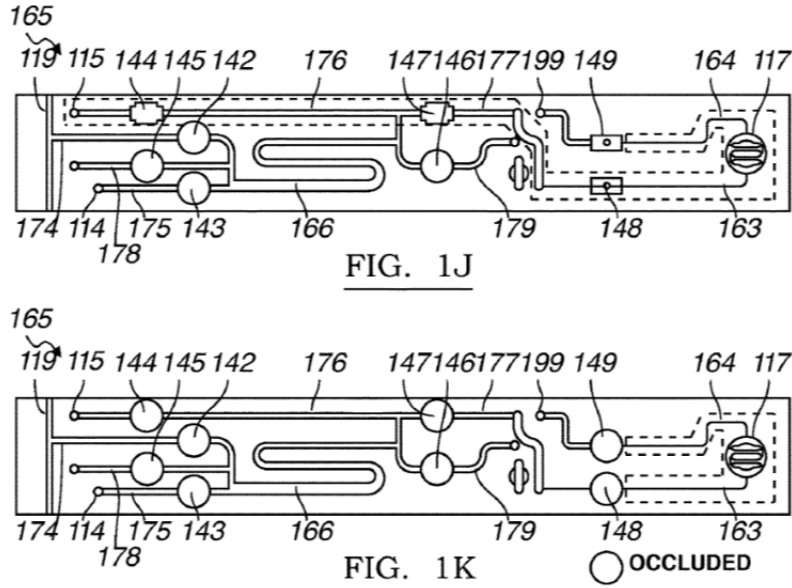
Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1249 488 1381 524">FIG. 1J</p> <p data-bbox="1249 789 1381 824">FIG. 1K</p> <p data-bbox="1493 789 1661 824">○ OCCLUDED</p> <ul data-bbox="842 854 1892 959" style="list-style-type: none"> • U.S. Patent No. 8,738,887 at 15:4-6 (“A fluidic pathway 165 may also further comprise an end vent 199, which functions to prevent any fluid from escaping the microfluidic channel.”)
10(g)	wherein the first valve and the second valve are configured to isolate the reaction chamber from the inlet and the vent to prevent movement of fluid into or out of the reaction chamber,	<p data-bbox="793 1003 1816 1105">In the accused microfluidic substrate, the first valve and the second valve are configured to isolate the reaction chamber from the inlet and the vent to prevent movement of fluid into or out of the reaction chamber.</p> <p data-bbox="793 1146 1902 1292"><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul data-bbox="842 1295 1902 1398" style="list-style-type: none"> • “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

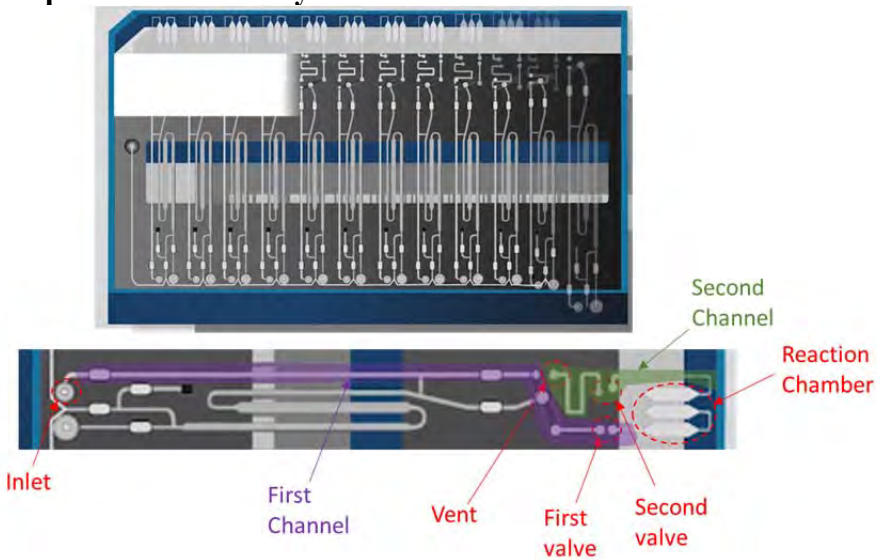
Claim	Claim Language	Infringement Evidence
		 <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module,

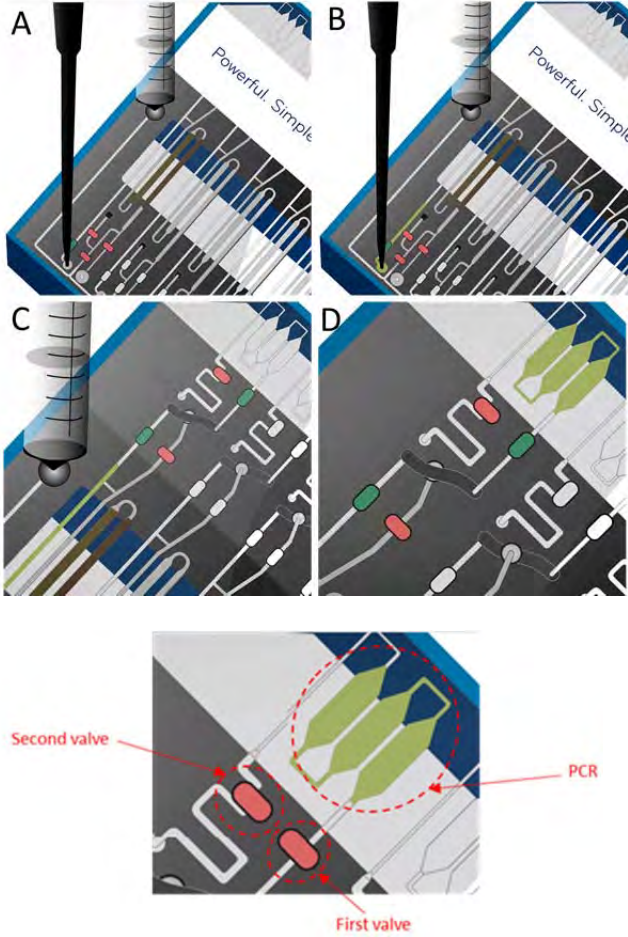
Claim	Claim Language	Infringement Evidence
		<p>the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads.</p> <ul style="list-style-type: none"> • Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber. <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve

Claim	Claim Language	Infringement Evidence
		<p>guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p>

Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> US Patent No. 9,738,887 at 12:11-19 (“When not in operation, however, the normally closed position 43 is configured to prevent leakage and/or fluid bypass. The normally closed position may also be held closed by an occluding object, to prevent leakage even under pressure provided by a fluid delivery system, or under pressure experienced during a high temperature step (e.g., thermocycling) to prevent evaporation of a sample undergoing thermocycling.”) US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) US Patent No. 9,738,887 at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="1297 488 1430 521">FIG. 1J</p> <p data-bbox="1297 792 1430 824">FIG. 1K</p> <p data-bbox="1541 792 1703 824">○ OCCLUDED</p> <ul style="list-style-type: none"> <li data-bbox="842 857 1892 1214">US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
10(h)	wherein the first valve is spatially separated from the inlet and the second valve is spatially	In the accused microfluidic substrate, the first valve is spatially separated from the inlet and the second valve is spatially separated from the vent.

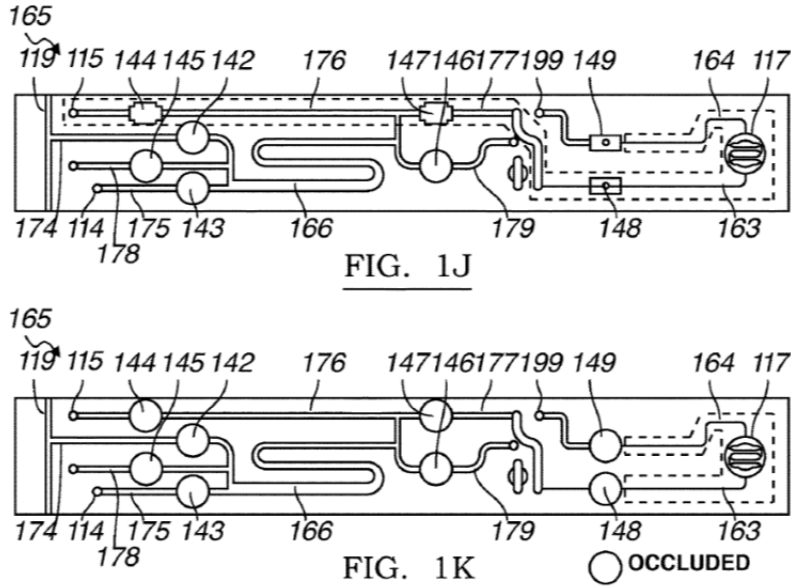
Claim	Claim Language	Infringement Evidence
	separated from the vent,	<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59  <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08

Claim	Claim Language	Infringement Evidence
		 <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> Claim 29. A method for processing and detecting nucleic acids within a cartridge having a fluidic pathway including a set of occlusion positions defined by an elastomeric layer of the cartridge, the method comprising: aligning the cartridge at a cartridge platform of a molecular diagnostic module,

Claim	Claim Language	Infringement Evidence
		<p>the cartridge platform having a set of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots and an actuator that provides relative displacement between the cartridge platform and the set of pins; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a first subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway at a first subset of the set of occlusion positions, thus defining a first truncated fluidic pathway passing through a magnetic field for controlling a flow through the fluidic pathway; capturing a sample of nucleic acids bound to magnetic beads within the first truncated fluidic pathway, by the magnetic field; and moving the cam module, thereby displacing a second subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude the fluidic pathway, through the elastomeric layer, at a second subset of the set of occlusion positions, thus defining a second truncated fluidic pathway containing the sample of nucleic acids bound to magnetic beads.</p> <ul style="list-style-type: none"> • Claim 30. The method of claim 29, further comprising: delivering a wash solution into the second truncated fluidic pathway through a fluid port to facilitate production of a volume of nucleic acids delivering the volume of nucleic acids through a reagent port coupled to the fluidic pathway; receiving the volume of nucleic acids combined with a volume of molecular diagnostic reagents to produce a nucleic acid-reagent sample; occluding the fluidic pathway at a third subset of the set of occlusion positions, thus defining a third truncated fluidic pathway coupled to a detection chamber; and delivering the nucleic acid-reagent sample, through the third truncated fluidic pathway, to the detection chamber. <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> • Claim 12. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer comprising a sample port and a detection chamber; an elastomeric layer; an intermediate substrate including a set of valve

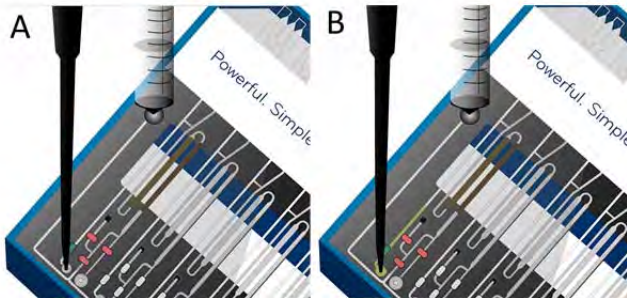
Claim	Claim Language	Infringement Evidence
		<p>guides, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface defines the set of valve guides with a set of openings that provide access to the elastomeric layer; and a fluidic pathway, formed by at least a portion of the first layer and a portion of the elastomeric layer, wherein the fluidic pathway is fluidically coupled to the sample port and the detection chamber and comprises a first and second branch extending downstream from a junction, and is configured to be occluded at a set of occlusion positions upon manipulation of the elastomeric layer through the set of valve guides, wherein a first occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the first branch and a second occlusion position of the set of occlusion positions is positioned along the fluidic pathway downstream of the junction and upstream of the second branch, wherein the set of occlusion positions comprises a normally open position and a normally closed position, wherein the normally open position comprises a first surface of the fluidic pathway at the first layer and a second surface of the fluidic pathway at the elastomeric layer, wherein a void defined between the first surface and the second surface is configured to transition to a closed state upon occlusion by an occluding object applied to the elastomeric layer during operation; wherein the normally closed position is defined by a region of the fluidic pathway, at the first layer that extends toward and abuts the elastomeric layer in preventing fluid bypass at the region; wherein a first truncated pathway, including the normally open position and the first branch and excluding the second branch, is defined upon manipulation of the fluidic pathway at the first and second occlusion positions, and wherein a second truncated pathway, including the normally closed position and the second branch and excluding the first branch, to the detection chamber is defined upon manipulation of the fluidic pathway at the first and second occlusion positions.</p>

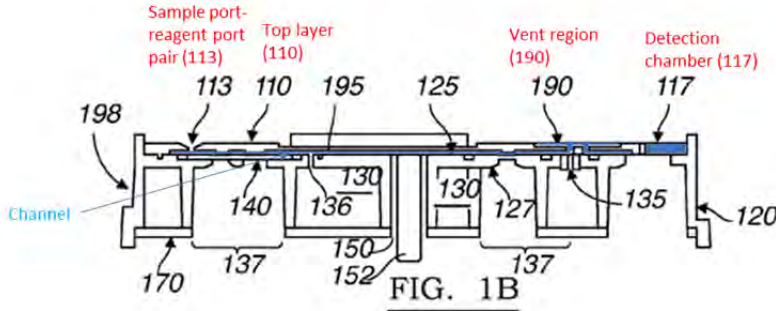
Claim	Claim Language	Infringement Evidence
		<ul style="list-style-type: none"> US Patent No. 9,738,887 at 17:27-49 (“Thereafter in the first embodiment, as shown in FIG. 11, the occlusions at the first and third occlusion positions 142, 144 may be reversed, defining a seventh truncated pathway, and the entire released nucleic acid sample (e.g. -20 microliters) may be aspirated out of the microfluidic cartridge through the reagent port 115. This released nucleic acid sample is then used to reconstitute a molecular diagnostic reagent stored off of the microfluidic cartridge 100. During the reconstitution, the occlusion at the sixth occlusion position 147 may be reversed, and the fluidic pathway 165 may be occluded at the first occlusion position 142 to form an eighth truncated pathway, as shown in FIG. 1J. Once reconstitution of the molecular diagnostic reagent with the released nucleic acid sample is complete and well mixed, the reconstituted mixture may then be dispensed through the reagent port 115, through the eighth truncated pathway, and to the detection chamber 117, by using a fluid handling system to push the seventh occlusion position [148] (normally closed) open. The detection chamber 117 is completely filled with the mixed reagent-nucleic acid sample, after which the fluidic pathway 165 is occluded at the third, sixth, seventh and eighth occlusion positions 144, 147, 148, 149, defining ninth truncated pathway, as shown in FIG. 1K. Other pathways of the set of fluidic pathways 165 may be similarly configured to receive a reagent-nucleic acid mixture. An external molecular diagnostic system and/or module may then perform additional processes, such as thermocycling and detection, on the volume of fluid within the detection chamber 117.”) US Patent No. 9,738,887 at at Figs. 1J and 1K:

Claim	Claim Language	Infringement Evidence
		 <p>FIG. 1J</p> <p>FIG. 1K</p> <p>○ OCCLUDED</p> <ul style="list-style-type: none"> US Patent No. 9,738,887 at 16:4-25 (“In the first embodiment, the set of occlusion positions 141 also comprises a sixth occlusion position 147 located along the vent segment 177 upstream of the vent region 190, a seventh occlusion position 148 located along the segment running to the detection chamber 163, and an eighth occlusion position 149 located along the segment running away from the detection chamber 164. In the first embodiment, the first, second, third, fifth, and sixth occlusion positions 142, 143, 144, 146, 147 are normally open positions 42 and the fourth, seventh, and eighth occlusions positions 145, 148, 149 are normally closed positions 43, as shown in FIG. 1C.”)
10(i)	wherein the reaction chamber, the first channel, and the second channel are formed in a first side of the microfluidic substrate,	On information and belief, in the accused microfluidic substrate, the reaction chamber, the first channel, and the second channel are formed in a first side of the microfluidic substrate.


Claim	Claim Language	Infringement Evidence
		<p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent port, the fluid port, and the detection chamber. U.S. Patent No. 9,738,887 at Fig 1B <p>FIG. 1B</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 13:65-14:2. (“A fluidic pathway 165 of the set of fluidic pathways 160 may comprise portions (i.e. microfluidic channels) that are located on both sides of the top layer 110, but is preferably located primarily on the bottom side of the top layer (in the orientation shown in FIG. 1B).”) U.S. Patent No. 9,738,887 at 14:19-14:28. (“In one variation, in the orientation of the microfluidic cartridge 100 shown in FIG. 11B, a fluidic pathway 165 is preferably located primarily on the bottom side of the top layer 110, comprising a segment running to a vent region 190 on the top side of the top

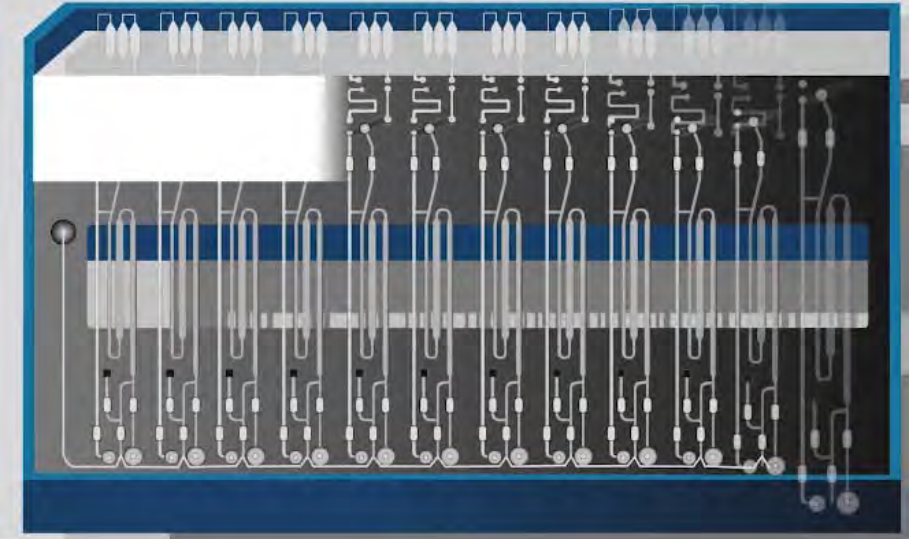
Claim	Claim Language	Infringement Evidence
		<p>layer 110. All other segments of the fluidic pathway 165 are preferably located on the bottom side of the top layer 110, allowing the fluidic pathway 165 to be sealed by the film layer 125 without requiring a separate film layer to seal channels located on the top of the top layer 110.”)</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,738,887 at 2:37-49. (“As shown in FIGS. 1A-1C, an embodiment of a microfluidic cartridge 100 for processing and detecting nucleic acids comprises: a top layer 110 comprising a set of sample port-reagent port pairs 112 and a set of detection chambers 116; an intermediate substrate 120, coupled to the top layer 110 and partially separated from the top layer by a film layer 125, configured to form a waste chamber 130; an elastomeric layer 140 partially situated on the intermediate substrate 120; a magnet housing region 150 accessible by a magnet 152 providing a magnetic field 156; and a set of fluidic pathways 160, each formed by at least a portion of the top layer 110, a portion of the film layer 125, and a portion of the elastomeric layer 140.”) • U.S. Patent No. 9,738,887 at 3:26-31. (“As shown in FIGS. 1B and 1C, the top layer 110 preferably comprises a set of sample port-reagent port pairs 112, a fluid port 118, a vent region 190, a heating region 195 crossing a capture segment 166 of a fluidic pathway 165, and a set of detection chambers 116.”) • U.S. Patent No. 9,738,887 at 5:66-6:17 (“In a first variation, as shown in FIGS. 1A and 11B, each detection chamber 117 in the set of detection chambers comprises a serpentine-shaped channel 16 for facilitating analysis of a solution of nucleic acids mixed with reagents... In a specific example of the first variation, each serpentine-shaped channel 16 is injected molded into the top layer 110 of the microfluidic cartridge 100, and the three interconnected portions of the serpentine-shaped channel 16 are each 1600 μm wide by 400 μm deep.”)
10(j)	wherein the inlet and the vent are formed in a second side of	On information and belief, in the accused microfluidic substrate, the inlet and the vent are formed in a second side of the microfluidic substrate opposite the first side

Claim	Claim Language	Infringement Evidence
	the microfluidic substrate opposite the first side, and	<p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> “A series of microfluidic valves guides the PCR-ready solution through the cartridge into three thin PCR chambers and the amplification process begins.” <i>Id.</i> at 3:58-4:08  <p>US9738887 (Exhibit 31)</p> <ul style="list-style-type: none"> Claim 1. A cartridge, configured to facilitate processing and detecting of a nucleic acid, comprising: a first layer, defining a sample port, a reagent port, a fluid port, and a detection chamber; an elastomeric layer; an intermediate substrate coupled to the first layer, such that the elastomeric layer is situated between the intermediate substrate and the first layer, wherein the intermediate substrate defines a chamber with a corrugated surface directly opposing the first layer, wherein the corrugated surface defines a set of voids external to the chamber and accessible from a direction perpendicular to a broad surface of the first layer, and wherein at least a portion of the corrugated surface includes a set of openings that provide access to the elastomeric layer; and a fluidic pathway, wherein the fluidic pathway is fluidically coupled to the sample port, the reagent port, the fluid port, and the detection chamber. Claim 2. The cartridge of claim 1 wherein the fluidic pathway is formed by at

Claim	Claim Language	Infringement Evidence
		<p>least a portion of the first layer and a portion of the elastomeric layer, is configured to be occluded upon manipulation of the elastomeric layer through the set of openings of the corrugated surface, and is configured to transfer a waste fluid to the chamber.</p> <ul style="list-style-type: none"> Claim 4. The cartridge of claim 2, wherein the chamber of the corrugated surface includes a waste inlet coupled to the fluidic pathway and a waste vent situated at a first side of the fluidic pathway, and wherein the cartridge further comprises a vent region directly opposed to the waste vent at a second side of the fluidic pathway. U.S. Patent No. 9,738,887 at Fig 1B  <p>FIG. 1B</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at Abstract (“A microfluidic cartridge, configured to facilitate processing and detection of nucleic acids, comprising: a top layer comprising a set of cartridge-aligning indentations, a set of sample port-reagent port pairs, a shared fluid port, a vent region, a heating region, and a set of Detection chambers; an intermediate substrate, coupled to the top layer comprising a waste chamber; an elastomeric layer, partially situated on the intermediate substrate; and a set of fluidic pathways, each formed by at least a portion of the top layer and a portion of the elastomeric layer, wherein each fluidic pathway is fluidically coupled to a sample port-reagent port pair, the shared fluid port, and a Detection chamber, comprises a turnabout portion passing through the heating region, and is configured to be occluded upon deformation of the elastomeric layer, to transfer a waste fluid to the waste

Claim	Claim Language	Infringement Evidence
		<p>chamber, and to pass through the vent region”)</p> <ul style="list-style-type: none"> U.S. Patent No. 9,738,887 at 14:19-14:28. (“In one variation, in the orientation of the microfluidic cartridge 100 shown in FIG. 11B, a fluidic pathway 165 is preferably located primarily on the bottom side of the top layer 110, comprising a segment running to a vent region 190 on the top side of the top layer 110. All other segments of the fluidic pathway 165 are preferably located on the bottom side of the top layer 110, allowing the fluidic pathway 165 to be sealed by the film layer 125 without requiring a separate film layer to seal channels located on the top of the top layer 110.”) U.S. Patent No. 9,738,887 at 14:35-42. (“In this variation, the fluidic pathway 165 thus crosses the thickness of the top layer 110 upstream of the first segment running to the detection chamber 163, and crosses the thickness of the top layer 110 downstream of the segment running away from the detection chamber 164, and crosses the thickness of the top layer 110 to couple to a sample port 114 and a reagent port 115 on the top side of the top layer 110.”) U.S. Patent No. 9,738,887 at 23:52-60 (“The injection molding process also defines the shared fluid port 118 of the top layer 110, and the vent region 190, which is recessed 0.5 mm into the top surface of the top layer 110 (in the orientation shown in FIG. 11B), and is covered with a polytetrafluoroethylene membrane, which is hydrophobic, gas permeable, and liquid impermeable. A paper label is bonded with adhesive to the top layer 110 over the vent region 190, which serves to identify the cartridge and protect the vent region 190, as shown in FIGS. 11A and 11B.”)
10(k)	wherein the first valve in each of the plurality of sample lanes is operated independently of any other first valve.	<p>In the accused microfluidic substrate, the first valve in each of the plurality of sample lanes is operated independently of any other first valve.</p> <p><i>NeuMoDx_Quant_HCV_CVS_2018.pdf (Exhibit 18)</i></p> <ul style="list-style-type: none"> Describing “...microfluidic cartridges capable of performing independent sample processing and real-time PCR.”

Claim	Claim Language	Infringement Evidence
		 <p><i>NeuMoDx Molecular N96 and N288 Overview and Animation</i>, NEUMODX (Nov. 6, 2018, 3:50 PM), http://www.neumodx.com/our-solutions/ - linking to “VIDEO NeuMoDx™ WORKFLOW” hyperlink at https://player.vimeo.com/video/299307936. (Exhibit 16)</p> <ul style="list-style-type: none"> • “This is the NeuMoDx microfluidic cartridge. Each microfluidic cartridge contains 12 independent lanes which allows for processing of up to 12 samples simultaneously.” <i>Id.</i> at 1:49-1:59

Claim	Claim Language	Infringement Evidence
		 <p data-bbox="793 813 1877 889"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/, last visited May 31, 2019 (Exhibit 10)</p> <ul data-bbox="846 894 1913 1219" style="list-style-type: none"> • “NeuMoDx™ Molecular Systems provide the industry’s first true continuous random-access solution and is scalable to meet the needs of the modern clinical laboratory. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability. Room temperature stable reagents and consumables dramatically reduce waste resulting in unmatched flexibility. Liquid handling and transport is achieved through proven robotic technologies. Our proprietary and unitized microfluidic cartridge features independent lanes allowing for simultaneous processing of sample types and varying assays.” <p data-bbox="793 1256 1906 1328"><i>NeuMoDx™ Molecular Systems</i>, NEUMODX, http://www.neumodx.com/our-solutions/, last visited May 31, 2019 (Exhibit 11)</p> <ul data-bbox="846 1333 1877 1401" style="list-style-type: none"> • “NeuMoDx™ MOLECULAR SYSTEMS REVOLUTIONARY MOLECULAR DIAGNOSTIC SOLUTION Our patented, “sample to result”

Claim	Claim Language	Infringement Evidence
		<p>platform offers market-leading ease of use, true continuous random-access and rapid turnaround time while achieving [sic] optimal operational and clinical performance for our customers and their patients.”</p> <ul style="list-style-type: none"> • “The NeuMoDx™ Molecular Systems are a family of scalable platforms that fully integrate the entire molecular diagnostic process from “sample to result”. The NeuMoDx™ 288 and the NeuMoDx™ 96 Molecular Systems are fully automated, continuous random-access analyzers that utilize our proprietary NeuDry™ reagent technology, which integrates magnetic particle affinity capture and real time Polymerase Chain Reaction (PCR) chemistry in a multi-sample microfluidic cartridge. This technology, combined with a platform, uniquely incorporates robotics and microfluidics that result in higher throughput, improved performance and increased efficiency by eliminating the waste associated with technologies that required reconstitution of lyophilized reagents. <p>40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (Exhibit 19)</p> <ul style="list-style-type: none"> • “NeuMoDx™ Cartridge INSTRUCTIONS FOR USE... Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System... The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR.” <p>US9339812 (Exhibit 26)</p> <ul style="list-style-type: none"> • Claim 15. A method for processing and detecting nucleic acids from a set of biological samples with a cartridge having a set of fluidic pathways defined by an elastomeric layer, the method comprising: combining each biological sample of the set of biological samples with a quantity of magnetic beads to produce a set of nucleic acid-magnetic bead samples; aligning the cartridge at a cartridge platform of a molecular diagnostic module, the cartridge platform having a set

Claim	Claim Language	Infringement Evidence
		<p>of slots, and the molecular diagnostic module having a cam module contacting a set of pins aligned with the set of slots; transferring substantially all of each nucleic acid-magnetic bead sample of the set of nucleic acid-magnetic bead samples to a corresponding fluidic pathway of a set of fluidic pathways; moving the cam module by transitioning the actuator into an extended configuration, thereby displacing a subset of the set of pins through the set of slots of the cartridge platform, and thereby manipulating the elastomeric layer to occlude at least one fluidic pathway of the set of fluidic pathways at a subset of occlusion positions for controlling a flow through the fluidic pathway; and detecting nucleic acids using a set of detection chambers coupled to the set of fluidic pathways.</p> <ul style="list-style-type: none"> • U.S. Patent No. 9,339,812 at 10:63-65 (“The preferred variation allows independent control of 12 independent channels, corresponding to 12 different pathways for sample processing.”)